

**EPA REGISTRATION NUMBER 81041-1 – VOL. 1**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

DEC 14 2005

R. Bruce Jaeger  
Health & Environmental Horizons, Ltd  
2851 South Haven Road  
Annapolis, MD 21401

Subject: Label Amendment to Add Additional Sites  
Expel  
EPA Reg. No. 81041-1  
Your submission dated December 1, 2005

Dear Mr. Jaeger:

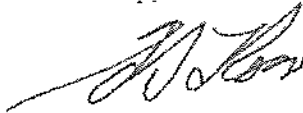
The amendment referred to above, submitted in connection with registration under Section (3) (c) (7) (a) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable subject to comments listed below. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

1. Change "products" to fabric/apparel throughout the labeling.
2. Move the misuse statement, "It is a violation of federal law.... etc. so that it appears above the bulleted items.

Since this label has been identified as the master label submit also the hang tag and garment labels. Note that these labels must be revised in accordance with comment 1 above.

If you have any questions in regard to this letter please feel free to contact me at 703-305-6100.

Sincerely,



George T. LaRocca  
Product Manager 13  
Insecticide Branch  
Registration Division (7505C)

enclosure

**EXPEL™**  
Insect Repellent Products

<b>ACTIVE INGREDIENT:</b>	% w/w*
Permethrin. ....	0.52%
<b>OTHER INGREDIENTS: (Fabric) .....</b>	<u>99.48%</u>
<b>Total .....</b>	100.00%

EPA Reg. No. 81041-1  
EPA Est. No. 81041-CHN-001

- This product has been treated with permethrin insect repellent.
- Repels mosquitoes, ticks, ants, flies, chiggers and midges.
- Do Not Dry clean – Dry cleaning removes active ingredient.
- Repellency remains effective for 25 washings for washable items: outerwear garments, sleeping bag covers, backpacks, bed netting and domestic animal care products (pet bedding, blankets, and netting).
- Repellency to mosquitoes remains effective for 6 months of exposure to weathering for non-washable items: tents, tarps, awnings, patio umbrella covers, kennel covers and stall covers.
- Wash separately from other items.
- Do Not Re-treat Expel product with other Permethrin insect repellent products.
- For protection of exposed skin, use in conjunction with an insect repellent registered for direct application to skin.
- Do not use for purposes other than originally intended.

**Storage and Disposal**

Do not contaminate water, food or feed by storage or disposal.

Disposal: Discard in trash when clothing/fabric or item is worn out. Do not reuse clothing/fabric for purposes other than originally intended.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

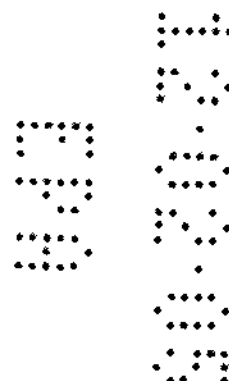
In addition, for labeling that is not permanently affixed, the removal "hang-tag" label must state the following:

Retain this tag for future reference on proper handling of this fabric/garment. This tag must not be removed except by consumer.

Manufactured by Bikel International, Inc.  
Chicago, IL

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated:**  
DEC 14 2005

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
81041-1



**Health & Environmental Horizons, Ltd**

2851 South Haven Road

Annapolis, MD 21401

410-974-6112/301-261-8491 (phone/fax)

December 1, 2005

George T. LaRocca (PM 13)  
Insecticide Branch/Registration Division (7505C)  
Office of Pesticide Programs  
Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Ave., NW  
Washington, DC 20460

Dear George;

SUBJECT: EPA Registration No. 81041-1, Amendment of Expel to Include Additional Use Cites With Revised Data Submitters List

On behalf of Bikel International, Inc., Health & Environmental Horizons, Ltd hereby submits an amendment to the registration to revise the label with additional use cites. The request to amend the label for Expel includes the following additional uses: tents, tarps, awnings, patio umbrella covers, kennel covers, stall covers, sleeping bag covers, backpacks, netting (bed netting), and domestic animal pet bedding. The existing registered uses approved for EPA Reg. No. 81041-1 are not changed. No other changes are requested at this time.

I greatly appreciate your advice and for meeting with me briefly on November 30 to review specific issues regarding the label for Expel. Although you had suggested a Me-Too Registration, we believe an amendment to the label would be more appropriate as the source product is [REDACTED]. We recognize those use cites are for manufacturing use only and we are therefore requesting end uses for many of the source product label cites. Our data submitters list has been revised to include additional use cites suggested by you, since they apparently have efficacy data supporting these additional cites. Please recognize, however, that there are published literature references and EPA reviewed documents (previously submitted) that provide efficacy assessments for permethrin on many of these use cites. I delivered a Registration Amendment to you on November 30 and you reviewed that submission with me and noted what has and has not been approved by EPA. We are amending that request with this submission, and that document is therefore superseded by this submission.

I urgently request that every effort be made to approve this amended registration as quickly as possible, recognizing the Christmas holiday will be here in 3-4 weeks and vacations and holidays may interrupt review time. Accordingly, we make the following submission.

Expel is a treated article registration that uses [REDACTED] to treat the various fabrics and articles that have been approved by EPA. An amended label that is inclusive of the label directions for use for EPA approved use cites is attached. Highlighted items on the label are those changes recommended by you. You recommended that the label be identical to Eastern Chemical's label (82108-1). All other statements on the label have been previously approved by EPA, October 26, 2004. There are no differences in directions for use for Expel from those uses that have already been approved by EPA.

Any and all documents referenced and submitted in the original Me-Too registration for Expel, EPA Reg. No. 81041-1, dated June 7, 2004, should be referred to as necessary to support this request. Additional sources of information are also cited in this request.

We respectfully request you give this request for an amended label full consideration. Please contact me directly if you have any questions, comments or requests for additional information regarding this request.

Sincerely,

  
R. Bruce Jaeger  
President

Atch: Amended Master label for Expel, dated 11/30/05

2005

G. LAYOCCA  
12-8-05

S: 87526		Regulatory Type: Product Registration - Section 3		Yes <input type="radio"/> No <input checked="" type="radio"/>		Print Letter Enter More Information Tracking
Application Type: Amendment		Disable: Yes <input type="radio"/> No <input checked="" type="radio"/>				
Company: 81041 BIKEL INTERNATIONAL INC		Y				
Risk Manager: Registration Division, Risk Management Team 13						
Product #: 81041-1		Product Name: BIKEL				
Me Too: 74843-2		Me Too: BUZZ OFF A SECT SHIELD A SECT REBELLEN				
Application Date: 01-Dec-2005		OPP Rec'd Date: 02-Dec-2005				
Front End Date: 05-Dec-2005		Risk Manager Sent Date: 06-Dec-2005				
FPS Due Date:		Negotiated Due Date:				
OPP Target Date:						
Fast Track: <input type="checkbox"/>		New Ingredient: <input type="checkbox"/>				
Receipt Description: AN AMENDMENT TO THE LABEL TO INCLUDE ADDITIONAL USE CITES						
[Empty Field]						
[Empty Field]						
[Empty Field]						

OPPIN Login | EPA-OPPIN Main - C... | N2106 10:24 AM



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

December 6, 2005

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

R. BRUCE JAEGER  
HEALTH & ENVIRONMENTAL HORIZONS, LTD.  
BIKEL INTERNATIONAL, INC.  
2851 SOUTH HAVEN RD  
ANNAPOLIS, MD 21401-

PRODUCT NAME: EXPEL  
COMPANY NAME: BIKEL INTERNATIONAL, INC.  
EPA FILE SYMBOL: 81041-1  
EPA RECEIPT DATE: 12/02/05

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 13, at (703) 305-6100.

Sincerely,

A handwritten signature in cursive script, appearing to read "J. White".

Front End Processing Staff  
Information Services Branch  
Information Technology & Resources Management Division



## Fee for Service



This package includes the following

- ☐ New Registration
- ☒ Amendment

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_\_

Risk Mgr. 13

Receipt No.

S-

787528

EPA File Symbol/Reg. No.

81041-1

Pin-Punch Date:

12/2/05

☒ This item is NOT subject to FFS action. **NON - FEE**

Action Code:

Requested:

Granted:

Amount Due: \$ \_\_\_\_\_

Parent/Child Decisions:

Reviewer: RKumar

Date: 12-6-05

Remarks:

*Efficacy data needed, but cite-all used to address any additional data requirements.*

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060. Approval expires 2/28/95.

EPA	United States	Registration	OMB Identifier Number
	Environmental Protection Agency	<input checked="" type="checkbox"/> Amendment	
	Washington, DC 20460	Other	

### Application for Pesticide - Section I

1. Company/Product Number 81041-1	2. EPA Product Manager George LaRocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Expel	PM#13	
5. Name and Address of Applicant (Include ZIP Code) Bikel International, Inc. 5765 N. Lincoln Ave., Suite 225 Chicago, IL 60659 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3a(3)(b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No. 82108-1, Eastern Insect Repellent Gear	

### Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II). Request is for an amendment to the label to include additional use cites supported by revised data submitters list. Additional use cites include: tents, tarps, awnings, patio umbrella covers, kennel covers, stall covers, sleeping bag covers, backpacks, bed netting, and pet bedding. Source product label lists these uses and data submitters list provides supporting product performance references.

### Section - III

1. Material This Product Will be Packaged in:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) <u>Extruded material</u>
* Certification must be submitted	If "Yes", Unit No. per container Packaging wgt.	If "Yes", Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container. Not applicable		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Method in Which label is Applied to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <u>Cloth tag attached to garment/fabric</u> <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name R. Bruce Jaeger	Title President; Health & Environmental Horizons, Ltd	Telephone No. (include Area Code) 301-261-8491
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) 
2. Signature 	3. Title President Health & Environmental Horizons, Ltd	
4. Typed Name R. Bruce Jaeger	5. Date December 1, 2005	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete

White - EPA File Copy (original) Yellow - Applicant Copy

Form approved, OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.



United States  
Environmental Protection Agency  
Washington, DC 20460  
**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address  Bikel International, Inc. 5765 N. Lincoln Ave., Suite 225 Chicago, IL 60659	EPA File Symbol/Registration Number  81041-1
	Product Name  EXPEL
	Date of Confidential Statement of Formula (EPA Form 8570-4)  02/10/2004

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

PERMETHRIN

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(a)(2) or (3)

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☒ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Permethrin	[REDACTED]	[REDACTED]
Signature 	Name and Title Robert B. Jaeger, President, H&EH	Date 11/30/2005

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA  
Copy 2 - Applicant copy



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Bikal International, Inc./5765 N. Lincoln Ave., Suite 225/Chicago, IL 60659/773-817-1322	EPA Registration Number/File Symbol 81041-1
Active Ingredient(s) and/or representative test compound(s)	Date 11/29/05
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	Product Name EXPEL

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☒ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

11/31/05

Typed or Printed Name and Title

Robert B. Jaeger, President, W&E, Ltd



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
1200 Pennsylvania Avenue, N.W.  
WASHINGTON, D.C. 20460

Form Approved OMB Nos. 2070-0060, 2070-0057,  
2070-0107, 2070-0122, 2070-0164

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2022T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date December 1, 2005 EPA Reg No./File Symbol 81041-1 Page 1 of 1

Applicant's/Registrant's Name & Address Bikel International, Inc.  
5765 N. Lincoln Ave., Suite 225, Chicago, IL 60659  
Product EXPTEL

Ingredient Permethrin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-2 thru 63-5	Product Chemistry	Cite All	Valent Bioscience Corp.	Pay	
63-7 thru 63-13	Product Chemistry	Cite All	Valent Bioscience Corp.	Pay	
81-1 thru 81-6	Acute Toxicology	Cite All	Bayer Crop Science	Pay	
91-4	Product Performance	Cite All	Bayer Crop Science	Pay	
91-4	Product Performance	Cite All	Eastern Chemical, LLC	Pay	
91-4	Product Performance	Cite All	Public record/literature	PL	
91-4	Product Performance	Cite All	Coulston Products, Inc.	Pay	
91-4	Product Performance	Cite All	US Department of the Army	Pay	
151-10	Product Chemistry	46208401	Bikel International	Own	
151-11	Product Chemistry	46208402	Bikel International	Own	
151-12	Product Chemistry	46208403	Bikel International	Own	
151-175	Product Chemistry	46288101	Bikel International	Own	

Signature

Name and Title Robert B. Jaeger, President  
Health & Environmental Horizons, Ltd

Date 12/1/05

EPA Form 8570-35 (12-2005) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1200 Pennsylvania Avenue, N.W.  
WASHINGTON, D.C. 20460

Form Approved OMB Nos. 2070-0060; 2070-0057;  
2070-0107; 2070-0122; 2070-0164

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for re-registration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date December 1, 2005 EPA Reg No./File Symbol 81041-1 Page 1 of 1

Applicant's/Registrant's Name & Address Bikel International, Inc.  
5765 N. Lincoln Ave., Suite 225, Chicago, IL 60659  
Product EXPEL

Ingredient: Permethrin		Submitter	Status	Note

Signature Name and Title Robert B. Jaeger, President  
Health & Environmental Horizons, Ltd Date 12/1/05

# INSTRUCTIONS FOR DATA MATRIX

**INSTRUCTIONS:** Identify all data submitted or cited and all submitters from whom permission has been received or to whom offers to pay have been sent by entering sufficient information in the attached matrix (photocopy and attach additional pages as necessary). Complete all columns; omission of essential information will delay approval of the registration/re-registration. On each page enter the data. Applicant's Registrant's name, EPA Registration Number or application file symbol of the product, ingredient, page number, and total number of pages.

The Data Compensation Form entitled "Certification with Respect to Citation of Data" and the Data Matrix will be publicly available, except for the Guideline Reference Number, Guideline Study Name, and MRID Number columns after the registration/re-registration of this product has been granted or once this form is received in response to a Data-Call-In Notice. However, the information in the Guideline Reference Number, Guideline Study Name, and MRID Number columns is available through the Freedom of Information Act in association with the EPA Registration Number.

**Registrant:** Identify the active ingredient(s) in this product for which data are cited. The active ingredient(s) are to be identified by entering the chemical name and the CAS registry number. Begin a new page for each separate active ingredient for which data are cited. If bridging data from a related chemical or representative test compound are cited, enter the identity of that chemical/representative test compound including the EPA Registration Number/File Symbol if appropriate.

If the cite-all method is used for all data supporting this particular ingredient, enter "CITE-ALL" in the Guideline Reference Number column and leave the Guideline Study Name column blank. If the cite-all method is used for a particular Guideline Reference Number enter "CITE-ALL" in the MRID Number column on the line for that Guideline Reference Number. In either case, enter all submitters to whom offers to pay have been sent on subsequent lines. [Note: if the selective method of support is used and written authorization (letter of permission) is provided, the individual Guideline Reference Number, Guideline Study Name, and MRID Number columns must still be completed.] *Otherwise:*

**Guideline Reference Number:** Enter on separate lines in numerical order the Guideline Reference Numbers from 40 CFR Part 158 for all studies cited to support the registration/re-registration for this ingredient.

**Guideline Study Name:** For each Guideline Reference Number cited, enter the corresponding Guideline Study Name.

**MRID Number:** For each individual study cited in support of a Guideline Reference Number and Guideline Study Name, enter the Master Record Identification (MRID) Number listed in the Pesticide Document Management System (PDMS). Enter only one MRID Number on each line. Note that more than one MRID Number may be required per Guideline Reference Number. Note: Occasionally a study required to maintain a registration/re-registration is not associated with a Guideline Reference Number and Guideline Study Name. In such case, enter the MRID Number(s) for the study(ies).

**Submitter:** Using the most recent Data Submitters List, identify the Original Data Submitter with their current address for each study cited. The EPA assigned company number or other abbreviation may be used. Clearly explain any variations (alternate addresses, data owners not on the Data Submitters List, etc.) in footnotes to this table.

**Submitter:** Enter one of the following codes for each study cited, as appropriate:

**OWN:** I am the Original Data Submitter for this study.

**EXC:** I have obtained written permission of the Original Data Submitter to cite this exclusive-use study in support of this application.

**PER:** I have obtained the permission of the Original Data Submitter to use this study in support of this application.

**OLD:** The study was submitted more than 15 years ago and all periods of compensation have expired.

**PL:** The study is in the public literature.

**PAY:** I have notified in writing the Original Data Submitter or, if the cite-all method is used, all companies listed in the most current Data Submitters List for this ingredient, and have offered to pay compensation in accordance with FIFRA sections 3(c)(1)(F) and/or 3(c)(2)(B), and (b) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study(ies).

**GAP:** This Guideline data requirement is a data gap as defined in 40 CFR sections 152.83(a) and 152.96.

**FOOT:** If, in writing the Registrant's exemption for this ingredient only, Other columns of this line should be marked "NA". However, if this product is to be registered/re-registered for additional uses for which the purchased EPA registered ingredient is not supported, additional data must be submitted or cited here to support those uses.

**Notes:** If additional explanation is needed, enter a footnote number in this column and attach the corresponding explanation.

**\*Product ingredient source information may be entitled to confidential treatment\***

Attachment: List of supporting EPA documents for treated article use for Permethrin, chemical code 109701:

- (1) July 31, 1989. Memorandum. 4 pages. Curt Lunchick. Non-dietary Exposure Branch. Registration of Permethrin for Military Use. HED Project #9-1356.
- (2) Undated. Review. 3 pages. Registration Division. RD Risk Assessment - Astex Mattress Cover. EPA File Symbol 71012-R.
- (3) Undated. Memorandum. 4 pages. George Tompkins. Special Review & Reregistration Division. [Reviews studies dated 1994] Review Three Exposure Assessments for Permethrin. EPA Reg. No.: 279-3051, 3083, 3014, 3059. MRIDs 43342601, 43324801, 43355501.
- (4) November 21, 1989. Memorandum. 24 pages. Edwin Budd. Toxicology Branch. EPA Reg. Nos. 50404-L and 50404-A. Permethrin Arthropod Repellent (50404-L) for Use on Military Uniforms and Fabrics and Coulston's Permanone Tick Repellent...Tox Review 007624.
- (5) July 27, 1990. Memorandum. 16 pages. Roger Gardner. Toxicology Branch I. Permanone (Permethrin) Tick-Repellent Dermal Absorption Data. Tox Review 008012. Attachment following:

June 20, 1990. Memorandum. John Doherty. Toxicology Branch I. EPA Id#63120-R, -E, and -G. Permethrin: Request from the military for the registration of three products for use on battle dress uniforms and clothing and bed netting and other fabrics. Tox Review 008012.

(6)

- (7) June 5, 1995. DER. 5 Pages. John Doherty. Toxicology Branch I. "Permethrin: Skin Sensitization Study". MRID No. 410311-06. Tox Review No. 011574.
- (8) June 13, 1995. Memorandum. 21 pages. John Doherty. Toxicology Branch I. EPA Id No. 109701. Permethrin: Review of a series 81-6 dermal sensitization study (guinea pig maximization test) and a series 85-2 dermal penetration study. Tox review 011574. MRID 41831106, 43169001.
- (9) April 29, 1996. Memorandum. 3 pages. Carol Glasgow. Registration Support Branch, RD. EPA File Symbol 4816-688 Permanone Multi-Purpose 10% E.C. reevaluation of tox category, primary dermal irritation. MRID 43895001.
- (10) February 22, 2001. Memorandum. 11 pages. Steven Weiss. Registration Action Branch HED. Review of Permethrin Rub-Off Trial from Astex Mattress Liners. MRID #45256001.
- (11) April 26, 2001. Review. 3 pages. Vern McFarland. Insecticide Branch. Efficacy Review of Unicorn .50% Permethrin; Provide references in support of the too registration of a new product containing an old chemical on the basis of the old all method.
- (12) EPA letter of approval and file for EPA Registration No. 81401-1, dated October 26, 2004.



Atlanta

Denver

Los Angeles

Philadelphia

McKenna Long  
& Aldridge, LLP  
Attorneys at Law

1900 K Street, NW • Washington, DC 20006  
202.496.7500 • Fax: 202.496.7756  
www.mckennalong.com

San Diego

San Francisco

Washington, DC

Brussels

JOHN D. CONNER, JR.  
(202) 496-7649

EMAIL ADDRESS  
jconnersjr@mckennalong.com

December 6, 2005

BY E-MAIL AND U.S. MAIL

George T. LaRocca (PM13)  
Insecticide Branch/Registration Division (7505C)  
Office of Pesticide Programs  
Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, NW  
Washington, D.C. 20460

Re: EPA Registration 81041-1

Dear Mr. Larocca:

Our firm represents Bikel Company, Ltd. ("Bikel"), the registrant of EXPEL™ (EPA Registration No. 81041-1). Iguana LLC ("Iguana") is the supplemental registrant/distributor of Pop-Up Bed Net (EPA Registration No. 81041-1-66306). We have been advised by the Defense Logistics Agency, Defense Supply Center Richmond ("DSCR") and the Armed Forces Pest Management Board ("AFPMB") that EPA's Office of Pesticide Programs ("OPP"), Registration Division ("RD"), has issued an opinion that EXPEL's registration, which permits the sale and distribution of permethrin-treated "garment/fabric," does not permit the sale and distribution of permethrin-treated bed netting. Acting on RD's opinion, the AFPMB removed Iguana from the list of eligible source suppliers for the treated bed netting. DSCR, acting on RD's opinion and the AFPMB decision to remove Iguana as a source supplier, then issued a stop work order affecting all of Iguana's government contracts for the treated bed netting. Iguana is a certified small business that relies heavily on defense contracts for existence. For this reason, RD's actions have caused and continues to cause Bikel and Iguana significant irreparable injury.

Although Bikel applied to RD on December 1, 2005, to amend its registration to substitute "product" for "garment/fabric" and to include bed netting among a list of "washable items," we respectfully submit that the sale and distribution of permethrin-treated netting is permitted under the terms of EXPEL™'s original garment/fabric registration. We are unaware of any FIFRA regulation or policy that states that bed netting is not fabric or, as Iguana was informed, that "fabric does not mean all fabrics." (11/29/2005 e-mail from Cliff Myers to Marla Redfearn.) (Enclosure 1.) Indeed, EPA's *Pesticide Assessment Guidelines (Subdivision G)*

George T. LaRocca  
December 6, 2005  
Page 2

define "fabric" as "all animal, plant, and synthetic fibers or blends to such materials." (*Guidelines* at § 95-14(a)(1) at page 276.) (Enclosure 2.)

RD is estopped to now contend that "fabrics" means something other than "fabrics," because Bikel's February, 2004, application expressly advised RD that the treated "garment/fabric" articles Bikel intended to sell and distribute under the EXPEL™ "garment/fabric" registration included treated netting. Bikel's application stated that it intended to treat garments and fabrics with [REDACTED]

Additionally, Bikel's Confidential Statement of Formula ("CSF") in support of its EXPEL™ application under "Components in Formulation" listed, in addition to permethrin, [REDACTED]

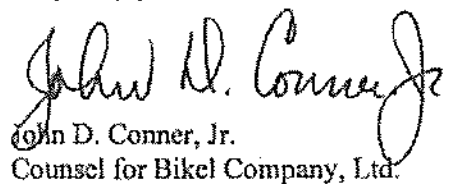
[REDACTED] Emphasis added.) Bikel's February 17, 2004, letter transmitting to you its application under "Proposed Uses" stated that EXPEL™ is "proposed for the use of treated fabric in the manufacture of articles such *netting*, tents, shelters, awnings, truck covers, hunting blinds, backpacks, sleeping bag shells; in outerwear garments ... and for domestic animal care products. ..." (2/17/2004 letter from R. Bruce Jaeger to George T. LaRocca (PM 13) (MRID 46208400) (emphasis added).) Finally, the Bikel application's "Description of Beginning Materials and Manufacturing Process" (MRID 46208402) and the application's "Discussion of Formation of Unintentional Ingredients During Expel Manufacturing Process" (MRID 46208403) both stated that the treated articles the registrant intended to manufacture included netting. As Bikel's application clearly and repeatedly informed RD that it intended to sell and distribute permethrin-treated netting -- as well other treated fabric articles that Bikel's application specifically enumerated -- under the EXPEL™ "garment/fabric" registration, the Agency is now estopped to assert that somehow treated-fabrics does not include treated bed netting fabric.

We respectfully submit that the sale and distribution of permethrin-treated bed netting under the EXPEL™ registration is truthful and not misleading. Iguana has made no claim in connection with the sale and distribution of its netting that differs from any claims made in connection with EXPEL's registration. (FIFRA § 12(a)(1)(A), (B)). We request the opportunity to meet with the Agency as soon as possible, and we request RD to immediately inform the AFPMB that the original EXPEL™ registration complies with the requirements of FIFRA. EPA's communication to the AFPMB and the subsequent removal of Iguana from the NSN Procurement Item Description as an eligible source supplier for treated bed netting are causing Iguana and Bikel continuing, irreparable harm. In the event that RD has forwarded any information on this matter to Office of Enforcement and Compliance Assurance ("OECA"), we request that RD send a copy of this letter to OECA as well.

George T. LaRocca  
December 6, 2005  
Page 3

Thank you for your assistance.

Very truly yours,

  
John D. Conner, Jr.  
Counsel for Bikel Company, Ltd.

cc: Marion Johnson  
Lois Rossi  
Jennifer A. Kerkhoff, Esq. (Counsel for Iguana LLC)  
Enclosures

**From:** Myers, Cliff (DSCR) [mailto:Cliff.Myers@dla.mil]  
**Sent:** Tuesday, November 29, 2005 1:15 PM  
**To:** Marla Redfeam  
**Cc:** Booker, Angela (DSCR); Williams, Susan C (DSCR); Bank, Marit (DSCR); Kerkhoff, Jennifer A.; Ernest G Stewart  
**Subject:** RE: Procurement Item Description Revised

**A formal letter is forthcoming from Ms Booker. Email response from EPA shown below along w/ attached AFPMB letter to DSCR provides rationale for removal. EPA considers bed netting to be different and not the same as fabric.**

**"Hi Cliff,**

**I spoke with George LaRocca and he verified that "fabric" does not mean all fabrics. If treating bed netting, it must be on the label. So if the distributor ... want bed netting on their label that they distribute, the basic registrant must amend their label to add directions for bed netting. The only product labeled for bed netting is 82108-1.**

**Have a great Holiday.**

**Linda Arrington  
Registration Division  
703 305 6249  
703 305 6920 (fax)"**

**If you have any additional questions, please advise.**

**R/**

**Clifford A Myers  
Chemist/AFPMB Pesticide Committee Chair/Notary Public  
Defense Supply Center Richmond  
ATTN: FAEAA  
8000 Jefferson Davis Hwy  
Richmond VA 23297-5809**

**804-279-3995**

**DSN prefix: 695**

**804-279-3653 Fax**

**804-651-4630 Cell**

**Cliff.Myers@dla.mil**

---

**From:** Maria Redfearn [mailto:marlar@rose.net]

**Sent:** Tuesday, November 29, 2005 12:52 PM

**To:** Myers, Cliff (DSCR)

**Cc:** Booker, Angella (DSCR); Williams, Susan C (DSCR); Bank, Marit (DSCR); 'Kerkhoff, Jennifer A.'; Ernest G Stewart

**Subject:** FW: Procurement Item Description Revised

Mr. Myers,

I am requesting a status on DSCR's review of the documents Iguana submitted on Monday 28<sup>th</sup> SEP per Marit Banks request. I have not had any contact from the technical staff due to any issues that arose from what Iguana is understanding was a protest by a company on Iguana's contract SPO406-W-8000, which was turned over to legal. Neither have I been forwarded a copy of the protest from legal; only issued a "Stop Work Order" that legal requested be issued to Iguana on November 1. We haven't even been informed as to what the protest concerned.

At this point Iguana has not been notified as why we were removed, or that we were even removed as a qualified supplier, therefore not given an opportunity to address the issue before we were removed. We discovered this through our standard operating procedures to check on the status of our items as a twice weekly review. We check the Progate, DSCR's site and Fed Biz Opps, frequently.

Iguana would like to resolve this issue promptly we do not want this to affect Iguana's eligibility for any contract awards for these items. Please inform Iguana by 4 pm today of DSCR's intentions.

Respectfully,  
Maria Redfearn  
Iguana, L.L.C.

---

**From:** Maria Redfearn [mailto:marlar@rose.net]

**Sent:** Monday, November 28, 2005 9:16 AM

**To:** Cliff Myers (cmyers@dla.mil)

**Cc:** 'ernest.stewart@iguanallc.com'; jennifer.kerkhoff@troutmansanders.com; 'Angela.Booker@dla.mil'

**Subject:** Procurement Item Description

Mr. Myers,

Could you please clarify why Iguana has been removed from the "Procurement Item Description" on NSN 3740-01-518-7310 & NSN 3740-01-518-4415?

Respectfully,  
Maria Redfearn  
Iguana, L.L.C.

on representative packages which should be examined for insect penetration, and for insects in the commodity, at frequent intervals throughout the tests.

(4) Residual protectants. Residual protectants should demonstrate efficacy comparable to a registered standard such as malathion.

(5) Vapors. (Reserved).

#### § 95-14 Fabric treatments.

This section concerns the data considerations for efficacy evaluation of pesticide products used for control of invertebrate pests of fabrics. The principle pests of fabrics include the webbing clothes moth and black carpet beetle.

(a) Definitions. The following definitions and explanations are of special importance in understanding this section:

(1) The term "fabrics" refer to all animal, plant, and synthetic fibers or blends to such materials.

(2) The term "temporary fabric treatments" refers to non-residual spray applications which kill fabric pests by contact action. Such treatments may require repeated application.

(3) The term "semipermanent fabric treatments" refers to residual chemical applications to wool, fur, or hair rugs, garments and blankets as coarse sprays or, in some cases, in dry cleaning solutions. To prepare for semipermanent mothproofing tests, the articles must be sprayed lightly but uniformly until the surfaces are moist but never soaked or saturated, and the sprayed articles thoroughly dried before testing.

(4) The term "permanent fabric treatments" refers to residual chemical impregnation in the fabric during the dye process. Test to determine effectiveness of these treatments require that the impregnated fabrics be tested before and after repeated washing, drycleaning, and other tests such as the performance tests of the American Association of Textile Chemists and Colorists.

(b) General considerations. The testing of a pesticide for household use should follow the same procedures as are appropriate for its commercial use.

(1) Test species. Although several species of insects attack woolen fabric and other animal fibers, the webbing clothes moth and black carpet beetle should be used in conducting efficacy tests for fabric protectants.

(2) Number of test insects. The number of test insects used is important in obtaining an accurate evaluation of these types of treatments, and at least 120 insects of each pest stage (larvae and adults) should be used for each test when evaluating temporary fabric protectants (direct contact sprays). When evaluating semipermanent and permanent fabric protectants,

use the number of insects set forth in the official CSMA "Textile Resistance Test", and the American Association of Textile Chemists and Colorists test method 24-1977.

(3) Number of trials. Four large-scale trials are generally preferred, and the number of trials can vary somewhat due to the accessibility of infestations, fluctuations in the pest population pressures, behavior, and other important considerations in the biology of the target pest. Because of the nature of fabric-insect problems, large scale trials are often impossible to conduct. However, for permanent fabric treatments, laboratory application data should be supplemented by pilot plant or mill scale application data.

(4) Observations. For agents providing temporary mothproofing, the test insects should be observed 24 and 48 hours after treatment and the percentage of knocked-down (KD) and dead plus moribund (D+M) insects recorded. Data should be presented in tabular form. When testing semi-permanent mothproofing products, the appropriate excrement-weight or fabric-weight loss data, mortality data, and the analytical results should be submitted in tabular form. Visual feeding damage ratings are useful.

(5) Application techniques and equipment. The data obtained must reflect the effectiveness of the test product when applied in commercial dry-cleaning and dyeing equipment. For general considerations, refer to § 90-5 (a)(3)(1).

(6) Evaluation and reporting procedures. The procedures used to evaluate product performance should be specified in the data. Reports should include mortality, fabric weight loss, excrement weight, analytical results, or other measures of determining the effectiveness of the test product. Data obtained should be based on the effect of the test product in protecting fabrics from damage by the larval stage of the pests. All observed adverse effects of the test product should be reported. For general considerations, refer to §§ 90-3 (c)(2) and (d)(1) through (4).

(c) Suggested performance standards. These suggested standards are determined on the basis of results obtained from laboratory tests following procedures set forth in the official CSMA "Textile Resistance Test," and the American Association of Textile Chemist and Colorists standard test methods 24-1977 and 28-1977. The performance standards cover the following fabric pests: webbing clothes moth and black carpet beetle.

(1) Temporary fabric treatments. Non-residual products that should provide almost complete (99%) control under repeated treatments every 30 days.

(2) Semi-permanent fabric treatments. Residual products should provide protection of the fabric as specified by CSMA and the American Association of Textile Chemists and Colorists test methods for 6 months to one year.

(3) Permanent fabric treatments. Residual products which are impregnated into the fabric during the dyeing process should provide protection of the fabric as specified by CEMA and the American Association of Textile Chemists and Colorists before and after the performance tests listed below:

<u>Manipulation</u>	<u>Minimum requirements</u>	<u>Maximum requirements</u>
Washing	5 times	10-15 times
Drycleaning - Stoddard solvent or perchloroethylene	5 times	10-15 times
Hot pressing	5 times	10-15 times
Sea water	5 immersions	
Perpiration:		
acid -	5 immersions	
alkaline -	5 immersions	
Light: Fade-O-meter	40 Standard Fading hours	100 Standard Fading hours
Abrasion	2000 revolutions - wear test machine 2000 revolutions for 6 minutes - Accelerotor	







27A4-2

Please Read All Instructions Before Completing this Form (Form must be typed)

Form Approved. OMB. No. 2070-0044



United States  
Environmental Protection Agency  
Office of Pesticide Programs (7502C)  
Washington, DC 20460

### Notice of Supplemental Distribution of a Registered Pesticide Product

#### Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

81041-1

Distributor Company Number

66306

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)

tent, shelter, net, garment, rugs, blanket

Distributor Product Name

IGUANA POP-UP BEDNETS

Name and Address of Distributor (Type; include ZIP code)

IGUANA, LLC  
2474 Magnolia Road  
Thomasville, GA 31792

#### Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

#### Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

MANAGING PARTNER

Date

9-29-04

#### Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

Date

Sept 28, 2004



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT 26 2004

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Mr. Robert B. Jaeger  
Agent for Bikel Company, Ltd  
Health& Environmental Horizons Inc.  
2851 South Hayden Rd  
Annapolis, Md 21401

Subject: Amendment: Finished Labels  
EPA Registration No. 81041-1  
Expel  
Your submission dated September 24, 2004

Dear Mr. Jaeger:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable. A stamped copy of the accepted label is enclosed for your records.

If you have any questions regarding this action, please contact me at (703) 305-6100.

Sincerely,

A handwritten signature in dark ink, appearing to read "G. LaRocca".

George T. LaRocca  
Product Manager 13  
Insecticide Branch  
Registration Division (7505C)

Enclosure: Stamped copy of label

Hang-tag on outside of garment (removable by consumer).

**EXPEL™**  
Insect Repellent Fabric/Apparel

<b>ACTIVE INGREDIENT:</b>	% w/w*
Permethrin. ....	0.52%
<b>OTHER INGREDIENTS: (Garment) .....</b>	<u>99.48%</u>
<b>Total .....</b>	100.00%

EPA Reg. No. 81041-1  
EPA Est. No. 81041-CHN-001

- This garment/fabric has been treated with Permanone 40 MFG Concentrate containing the insect repellent, Permethrin.
- Repels mosquitoes, ticks, ants, flies, chiggers, and midges.
- Do Not Dry clean – Dry cleaning removes active ingredient.
- Repellency remains effective for 25 washings.
- Do Not Re-treat garment/fabric with other Permethrin insect repellent products.
- For protection of exposed skin, use in conjunction with an insect repellent registered for direct application to skin.
- Wash treated garment/fabric separately from other clothing/fabric.

**Storage and Disposal**

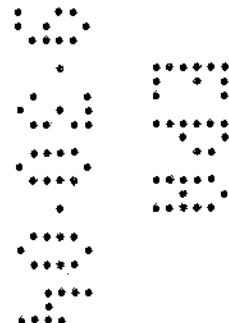
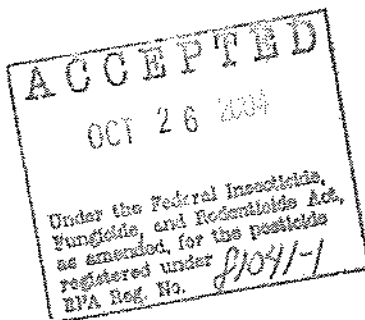
Do not contaminate water, food or feed by storage or disposal.

Disposal: Discard in trash when clothing/fabric is worn out. Do not reuse clothing/fabric for purposes other than originally intended.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Retain this tag for future reference on proper handling of this fabric/garment. This tag must not be removed except by consumer.

Manufactured by Bikel Company, Ltd.  
Seoul, Korea



Garment tag permanently attached to treated fabric/garment.

**EXPEL™**

Insect Repellent Fabric/Apparel

Do Not Dry Clean

Repels mosquitoes,

ticks, ants, spiders,

flies, chiggers

and midges.

Repellency remains  
effective for 25 washings.

Active Ingredient:

Permethrin

0.52% w/w

EPA Reg. No.

81041-1

EPA Est. No.

81041-CHN-001

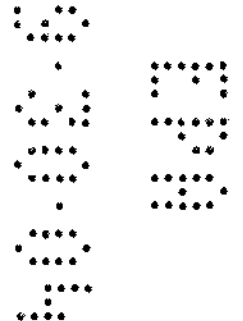
Dispose of fabric/garment

in trash. Wash separately

from other fabric/garment.

Refer to Hang Tag for  
more information.

This tag will comply with the universal size for such items, limited to what can be permanently attached to apparel, based on requirements of the garment and clothing industry.



Explore Registrations				
Reg Number:	81041-1	Reg. Type:	Product Registration - Section 3	Status:
Name:		EXPCEL		Conditionally Registered (13-Sep-2004)
<a href="#">View Registration Details</a>				
(No New Receipts)				
S	Submission Type	OPP Rec'd Date	Resubmission	Description
<div> <div> ...Decisions... <ul style="list-style-type: none"> <li>Data Requirements</li> <li>D: 346880; 81041-1; W01; ULTRA SMALL BUSIN</li> <li>S: 762287 6/3/2004; FFS Waiver Request; t</li> <li>D: 346879; 81041-1; V01; FEE REDUCTION (100</li> <li>D: 340273; 81041-1; R30; NEW PRODUCT; ME-T</li> <li>S: 761595 6/7/2004; Miscellaneous Receipt</li> <li>S: 760428 3/31/2004; New Registration; 810</li> <li>S: 754727 2/19/2004; New Registration; 810</li> </ul> </div> <div> <div>S: 768823 Reg #: 81041-1</div> <div>Submission Type: New Registration</div> <div>Resubmission? <input checked="" type="radio"/> Yes <input type="radio"/> No</div> <div>Decision #: 340273, R30, NEW PRODUCT, ME-TOO PRODUCT FAST TRACK</div> <div>Submitter Company: EXPCEL COMPANY, LTD.</div> <div>Application Date: 24-Sep-2004</div> <div>OPP Received Date: 30-Sep-2004 Date Sent to Risk manager: 01-Oct-2004</div> <div>Studies Included? <input type="radio"/> Yes <input checked="" type="radio"/> No Fast Track? <input checked="" type="radio"/> Yes <input type="radio"/> No</div> <div>Form A Signed? <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> None Date: </div> <div>Form B Signed? <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> None Date: </div> <div>Reviewer: Larocca, George</div> <div>Received DT: </div> <div>Enforceable Due DT: </div> <div>Admin Due DT: 29-Dec-2004 Response: D, 30-Sep-2004</div> <div>Priority Weight: </div> <div>Priority Points: </div> <div>Comments: submit revised finished labeling</div> </div> </div>				

second yucked

Health & Environmental Horizons, Ltd.  
2851 South Haven Rd.  
Annapolis, MD 21401  
Phone 410-721-7689  
Fax 301-261-3114

September 24, 2004

George T. LaRocca (PM 13)  
Insecticide Branch/Registration Division (7505C)  
Office of Pesticide Programs  
Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Ave., NW  
Washington, DC 20460

Dear George;

SUBJECT: EPA Registration No. 81041-1, Revisions To Label In Response to EPA  
Registration Approval Letter, dated 9/13/04

First, thanks for all of the assistance and advice you and your staff provided to us during our efforts to obtain the registration approval for Expel, EPA Registration Number 81041-1. The labels have been revised according to the conditions specified in your approval letter, dated 9/13/04. These revised labels are attached.

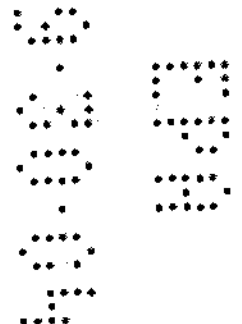
Once again, thanks for your assistance.

Sincerely,



Robert B. Jaeger  
President

Attachments: (1) Expel Garment Label, dated 9/24/04  
(2) Expel Hang-tag Label, dated 9/24/04





U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (H7505C)  
401 "M" St., S.W.  
Washington, D.C. 20460

EPA Reg. Number:

81041-1

Date of Issuance:

SEP 13 2004

Term of Issuance: Conditional

Name of Pesticide Product:

Expel

NOTICE OF PESTICIDE:

☒ Registration

☐ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (Include ZIP Code):

Bikel Company, Ltd  
Sudo Building 3<sup>rd</sup> Floor, 160-18 Samsung-Dong  
Kanganm-Ku, Seoul, Korea

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A), provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Make the following labeling changes:
  - a) Revise the EPA Registration Number to read "EPA Reg. No. 81041-1"
  - b) Change "may" to "must" in the statement "This tag may not be removed...".
3. Please submit two (2) copies of your final printed label for before your release the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

If you have any questions regarding this action, please contact BeWanda Alexander of my team at (703) 305-7460.

Signature of Approving Official:

George T. LaRocca, Product Manager (13), IB/RD (7505C)

Date:

September 13, 2004



Hang-tag on outside of garment (removable by consumer).

**EXPEL™**  
Insect Repellent Fabric/Apparel

<b>ACTIVE INGREDIENT:</b>	% w/w*
Permethrin.....	0.52%
<b>OTHER INGREDIENTS: (Garment) .....</b>	<u>99.48%</u>
<b>Total .....</b>	100.00%

EPA Reg. No. 81041-R  
EPA Est. No.

- This garment/fabric has been treated with Permanone 40 MFG Concentrate containing the insect repellent, Permethrin.
- Repels mosquitos, ticks, ants, flies, chiggers, and midges.
- Do Not Dry clean – Dry cleaning removes active ingredient.
- Repellency remains effective for 25 washings.
- Do Not Re-treat garment/fabric with other Permethrin insect repellent products.
- For protection of exposed skin, use in conjunction with an insect repellent registered for direct application to skin.
- Wash treated garment/fabric separately from other clothing/fabric.

**Storage and Disposal**

Do not contaminate water, food or feed by storage or disposal.

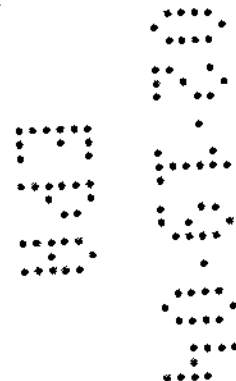
Disposal: Discard in trash when clothing/fabric is worn out. Do not reuse clothing/fabric for purposes other than originally intended.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Retain this tag for future reference on proper handling of this fabric/garment. This tag may not be removed except by consumer.

Manufactured by Bikel Company, Ltd.  
Seoul, Korea

ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
SEP 13 2004  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
81041-1



Expel  
2/9/04 Section 3 Registration MASTER Label  
Garment Tag

Garment tag permanently attached to treated fabric/garment.

EXPEL™

Insect Repellent Fabric/Apparel

Do Not Dry Clean

Repels mosquitoes,  
ticks, ants, spiders,  
flies, chiggers  
and midges.

Repellency remains  
effective for 25 washings.

Active Ingredient:

Permethrin

0.52% w/w

EPA Reg. No.

81041-R

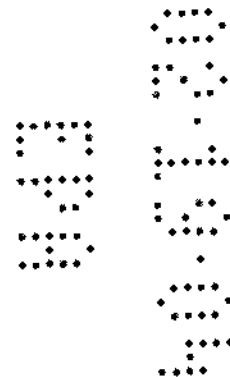
EPA Est. No.

81041-

Dispose of fabric/garment  
in trash. Wash separately  
from other fabric/garment.

Refer to Hang Tag for  
more information.

This tag will comply with the universal size for such items, limited to what can be permanently attached to apparel, based on requirements of the garment and clothing industry.



**Health & Environmental Horizons, Ltd**

2851 South Haven Road  
Annapolis, MD 21401  
301-261-3114 (phone/fax)

**FAX***3 pages*

DATE: September 7, 2004

TO: George LaRocca (PM13)  
Insecticide Branch/Registration Division (7505C)  
OPP  
EPA

FAX NO: 703-605-1225

FROM: Bruce Jaeger

MESSAGE: I have attached a revised copy of the Data Matrix, EPA Form 8570-35, dated 9/7/04, as requested. Unfortunately, this new form does not print uniformly and you cannot alter the print size, so some of it looks different. Hopefully this will suffice. I will provide a hard copy this week if I receive your approval. I have contacted both Valent and Bayer regarding use of their acute data and have offered to pay. I am requesting that they provide an authorization to you, but it probably will not arrive until next week. In the interim I hope this will suffice to move this action along and receive some good news for a change. Please let me know if there is anything else you need at this stage. The company has potential contracts that are contingent upon EPA's approval. Please call me when you get a chance (410-971-1784 or 410-721-7689)

Thanks again for your assistance.

Regards,

  
Bruce Jaeger





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
1200 Pennsylvania Avenue, N.W.  
WASHINGTON, D.C. 20460

Form Approved OMB Nos. 2070-0080; 2070-0057;  
2070-0107; 2070-0121; 2070-0164

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send this form to this address.

## DATA MATRIX

Date 9/7/04 [Revised]

EPA Reg No./File Symbol 910A1-R

Page 1 of 1

Applicant's/Registrant's Name &amp; Address

Bikei Company, Ltd Sudo Building 3rd Floor, 160-16 Samsung-Dong, Kangnam, Seoul, Korea

Product

EXPEL

Ingredient 40-2 HVC-00-6

Guideline Reference Number

Guideline Study Name

MRID Number

Submitter

Status

Note

63-2 thru 63-5

Product Chemistry

cite all

Valent Biosciences Corp

Pay

63-7 thru 64-13

Product Chemistry

cite all

Valent Biosciences Corp

Pay

61-1 thru 61-6

Product Performance

cite all

Public Record/Literature

Pay

151-10

Acute Toxicology

cite all

Bayer

Pay

151-11

Product Chemistry

46208401

Bikei Company

Own

151-12

Product Chemistry

46208402

Bikei Company

Own

151-13

Product Chemistry

46208403

Bikei Company

Own

151-14

Product Chemistry

46208401

Bikei Company

Own

151-15

Product Chemistry

46208401

Bikei Company

Own

151-16

Product Chemistry

46208401

Bikei Company

Own

151-17

Product Chemistry

46208401

Bikei Company

Own

151-18

Product Chemistry

46208401

Bikei Company

Own

151-19

Product Chemistry

46208401

Bikei Company

Own

151-20

Product Chemistry

46208401

Bikei Company

Own

151-21

Product Chemistry

46208401

Bikei Company

Own

151-22

Product Chemistry

46208401

Bikei Company

Own

151-23

Product Chemistry

46208401

Bikei Company

Own

151-24

Product Chemistry

46208401

Bikei Company

Own

151-25

Product Chemistry

46208401

Bikei Company

Own

151-26

Product Chemistry

46208401

Bikei Company

Own

151-27

Product Chemistry

46208401

Bikei Company

Own

151-28

Product Chemistry

46208401

Bikei Company

Own

151-29

Product Chemistry

46208401

Bikei Company

Own

151-30

Product Chemistry

46208401

Bikei Company

Own

151-31

Product Chemistry

46208401

Bikei Company

Own

151-32

Product Chemistry

46208401

Bikei Company

Own

151-33

Product Chemistry

46208401

Bikei Company

Own

151-34

Product Chemistry

46208401

Bikei Company

Own

151-35

Product Chemistry

46208401

Bikei Company

Own

151-36

Product Chemistry

46208401

Bikei Company

Own

151-37

Product Chemistry

46208401

Bikei Company

Own

151-38

Product Chemistry

46208401

Bikei Company

Own

151-39

Product Chemistry

46208401

Bikei Company

Own

151-40

Product Chemistry

46208401

Bikei Company

Own


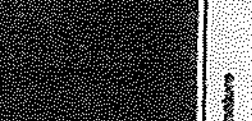
Signature *Robert B. Jaeger*

Name and Title  
Robert B. Jaeger, President, Health & Environmental Horizons, Ltd

Date  
9/7/04

EPA Form 8570-35 (12-2006) Electronic and Paper versions available. Submit only Paper version.

Agency Retains Original Copy

 <p><b>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY</b>          1200 Pennsylvania Avenue, N.W.          WASHINGTON, D.C. 20460</p>		Form Approved OMB No. 2070-0040; 2070-0057; 2070-0107; 2070-0122; 2070-0164	
<p><b>Paperwork Reduction Act Notice:</b> The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for revision and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden for Director, Collection Strategies Division (20227), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.</p>			
<b>DATA MATRIX</b>			
<b>Date</b> 9/7/04 [Revised]		<b>EPA Reg No./File Symbol</b> none	
<b>Applicant's Registrant's Name &amp; Address</b>  Bikel Company, Ltd Sudo Building 3rd Floor, 160-16 Samsung-Dong, Kangnam, Seoul, Korea		<b>Product</b> <b>EXPEL</b>	
		<b>Submitter</b>	<b>Status</b>
		Valent Biosciences Corp	Pay
		Valent Biosciences Corp.	Pay
		Public Records/Literature	R
		Bayer	Pay
		Bikal Company	Own
		Bikal Company	Own
		Bikal Company	Own
		Bikal Company	Own
<b>Signature</b>  Robert B. Jungner, President, Health & Environmental Hazards, Ltd		<b>Name and Title</b> Robert B. Jungner, President, Health & Environmental Hazards, Ltd	
		<b>Date</b> 9/7/04	

DATE OUT: 30/JUN/2004

FEED: PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [☐] End-Use Product [☒  
DP BARCODE: D304282 EPA RECEIVED DATE: 07/JUN/2004 FILE SYMBOL/REG #: 81041-R  
PRODUCT NAME: Expel MRID No 462084-01 10 -03 & 462881-01 NON-FOOD USE [☒  
COMPANY NAME: Bikel Company, Ltd. ACTION CODE: R30  
PPC NUMBERS OF THE TGA1 IN THE PRODUCT: 109701 DECISION NO.: 340273

FROM: Sami Malak, Chemist *Sami Malak*  
Technical Review Branch/RD (7505C)

TO: 13 George LaRocca/BeWanda Alexander  
Insecticide Branch/RD (7505C)

*SBW 6/20/04*

### INTRODUCTION:

The applicant, requested a "me-too" registration of subject product claiming its similarity to Buzz Off Insect Shield Apparel, Reg. No. 74843-2. In support of this action, the applicant included product chemistry data, a basic CSF dated 10/FEB/2004, a draft label EPA received on 19/FEB/2004, Formulator's Exemption Statement, Certificate With Respect to Citation of Data, and Data Matrix.

### FINDINGS:

1. The subject product was produced by a non-integrated formulation system, meaning that the technical source in the product is registered. The product contains 0.52% permethrin, Reg. No. [REDACTED]
2. The subject product, is an insect repellent fabric/apparel.
3. The subject product is substantially similar in composition to Buzz Off Insect Shield Apparel, Reg. No. 74843-2. Both product contain the same active ingredient at the same nominal concentration, upper/lower certified limits, and similar physical chemical properties.
4. Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with registration of the technical source, permethrin, Reg. No. [REDACTED]
5. The submitted product chemistry data is adequate and support "me-too" registration of subject product.
6. The label claim nominal concentration of 0.52% permethrin is consistent with that in the basic CSF and are in compliance with the regulations of PR Notice 91-2. Further, the storage and disposal statement and the physical or chemical hazards statement are in compliance with the regulations of 40CFR§156.78.
7. The proposed basic CSF dated 10/FEB/2004, was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed on the CSF are cleared for use in pesticide formulations intended for non-food uses.



CONCLUSIONS:

1. From the product chemistry view point, the subject product is substantially similar in composition to Buzz Off Insect Shield Apparel, Reg. No. 74843-2 (Finding 3).
1. The TRB has no objections for a "me-too" registration of subject product. Product's label EPA received on 19/FEB/2004 and basic CSF dated 10/FEB/2004 are acceptable as per Findings 6 & 7 above.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 10/FEB/2004 was included with this submission claiming confidentiality of some of the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI data was removed to Confidential Appendix A.
2. A GLP statement dated 10/FEB/2004 was included with this submission to the effect that the submitted studies do not fall within the scope of the GLP requirements of 40CFR§160.

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)

830-1550 Product Identity and Composition

The subject product was produced by a non integrated formulation system meaning that the technical source in the product is registered. The product contains 0.52 % permethrin, Reg. No. [REDACTED] plus cleared intentionally added inert ingredients (refer to product's basic CSF dated 10/FEB/2004).

830-1600 Description of Materials Used to Produce the Product:  
Refer to Confidential appendix A.

830-1650 Description of Formulation Process:  
Refer to Confidential appendix A.

830-1670 Discussion of Formation of Impurities:  
Refer to Confidential appendix A.

830-1700 Preliminary Analysis:  
Refer to Confidential appendix A.

830-1750 Certified Limits:  
Refer to Confidential appendix A.

830-1800 Enforcement Analytical Method:

Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with registration of the technical source, permethrin, Reg. No. [REDACTED]

**Identity, Composition, Formulation, and Analysis, Subgroup A, Series 830.1550 to 830.1800**  
**(40 CFR 158.155 to 158.180)**

Guideline Reference NO. (GRN 830.)/Title	Data Fulfilled	MRID No.
.1550 Product identity and composition	Y	462084-01
.1600 Description of materials used to produce the product	Y	462084-02
.1620 Description of production process	NA	
.1650 Description of formulation process	Y	462084-02
.1670 Discussion of formation of impurities	Y	462084-03
.1700 Preliminary analysis	NA	
.1750 Certified limits	Y	462881-01
.1800 Enforcement analytical method	Y	referenced

Explanations: Y = The requirements were fulfilled; N = The requirements not fulfilled; N/A = Not applicable; G = Data gap; U = Requires upgrading; I = Incomplete or in progress; W = Waived.

\*Product ingredient source information may be entitled to confidential treatment\*

\*Manufacturing process information may be entitled to confidential treatment\*

4

#### Confidential Appendix A

##### 830-1600 Description of Materials Used to Produce the Product:

The subject product was produced by a non integrated formulation system meaning that the technical source in the product is registered. The product contains 0.52 % permethrin, Reg. No. [REDACTED] plus cleared intentionally added inert ingredients intended for non-food uses (refer to product's basic CSF dated 10/FEB/2004),

##### 830-1650 Description of Formulation Process:

[REDACTED]

##### 830-1670 Discussion of Formation of Impurities:

The applicant reported no impurities  $\geq 0.1\%$  by weight were known to be formed during formulation and storage of the product. There was no chemical reaction in the process.

##### 830-1700 Preliminary Analysis:

Not required for this non-integrated product.

##### 830-1750 Certified Limits:

The applicant reported the same certified limits as those in product's (refer to product's basic CSF dated 10/FEB/2004).



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND  
TOXIC SUBSTANCES

TECHNICAL REVIEW BRANCH  
SIMILARITY CLINIC DETERMINATION

July 16, 2004

MEMORANDUM

Subject: Name of Pesticide Product: Expel  
EPA File Symbol: 81041-R  
DP Barcode: D304283  
Decision No: 340273  
PC Code: 109701 Permethrin

From: Bream Hanson, Toxicologist *BH*  
Technical Review Branch *sen*  
Registration Division (7505C)

To: BeWanda Alexander, RM Team 13  
Insecticide Branch  
Registration Division (7505C)

Applicant: Bikel Company, Ltd.  
Sudo Building 3<sup>rd</sup> Floor, 160-18 Samsung-Dong, Kangnam-Ku  
Seoul, Korea

FORMULATION FROM LABEL:

<u>Active Ingredient:</u>			<u>% by wt.</u>
109701	Permethrin	CAS No. 52645-53-1	0.52%
<u>Inert Ingredients:</u>			<u>99.48%</u>
Total:			100.00%

**ACTION REQUESTED:** The Risk Manager requests :

"Please review for substantially similar to EPA# 74843-2. Company has submitted a toxicology data waiver request. Included in this package is a copy of the label, CSF, waiver request justification, and cover letter. "

**BACKGROUND:** Bikel Company, Ltd. has applied for registration of Expel, EPA File Symbol 81041-R, claiming similarity to Buzz Off Insect Shield Apparel, EPA Reg. No. 74843-2. The submission includes a copy of the label, letter and waiver request for the proposed product, and CSF for both the proposed and cited products. The proposed and cited products are both garments containing 0.52% permethrin. The cited product was reviewed in two previous TRB memos (Redden, EPA File Symbol: 74843-E, D285609, 26/FEB/2003 and Backus, EPA File Symbol: 74843-E, D289867, 30/JUN/2003).

**RECOMMENDATIONS:** TRB has evaluated the formulations of the proposed product, 81041-R, and the cited product, 74843-2, and have found them to be substantially similar. Based on the latter TRB memo (Backus), we recommend the proposed product, EPA File Symbol 81041-R, use the same labeling as the cited product, EPA Reg. No. 74843-2. This product is not a solution or suspension, and its use as clothing does not require any special instructions. This action has made no determinations of the adequacy of the toxicological data which may have been submitted for the cited product.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND  
TOXIC SUBSTANCES

*cited  
memos*

June 30, 2003

MEMORANDUM

EPA File Symbol: 74843-E BUZZ OFF INSECT SHIELD APPAREL  
DP Barcode: D289867  
Decision Code: 214291  
Case No: 067402  
Submission: S629070  
PC Code: 109701 Permethrin, mixed cis, trans

From: Byron T. Backus, Ph.D., Toxicologist  
Technical Review Branch  
Registration Division (7505C)

To: Susan Stanton, PM 03  
Insecticide Branch  
Registration Division (7505C)

Registrant: BUZZ OFF INSECT SHIELD, LLC

**ACTION REQUESTED:** Review of an application for registration of garments containing 0.52% permethrin with insect repellent claims.

**BACKGROUND:** The registrant is citing two existing registered products in support of this application. Both of the currently registered products contain 0.5% permethrin as sole active, including BITE ARMOR (EPA Reg. No. 48139-11) which is used to treat clothing, as well as EPA Reg. No. 4816-696. The registrant is requesting waivers for all acute toxicity studies, based on the fact that the cited products are in toxicity category IV by all exposure routes and are not dermal sensitizers. Because of the low toxicity the final registered product would not have a signal word. The proposed ingredient

label for EPA File Symbol 74843-E is the following:

Active Ingredient:  
    Permethrin.....0.52%  
Garment.....99.48%

**COMMENTS AND RECOMMENDATIONS:**

1. After examining the information in this application, as well as the labels and uses of the cited products (EPA Reg. Nos. 4816-696 and 48139-11), TRB concludes that the proposed product, BUZZ OFF INSECT SHIELD, EPA File Symbol 74843-E, can be registered, subject to the comments below.
2. As the active ingredient at 0.52% is in toxicity category IV by all exposure routes and is not a dermal sensitizer, the signal word "CAUTION" is not required. This product, unlike the cited products EPA Reg. Nos. 4816-696 and 48139-11, is not a solution or suspension, and its use (as clothing) does not require any special instructions.
3. Because the cited product, EPA Reg. No. 48139-11, specifies that it is not to be used to treat underwear, hats, caps or inner clothing, a similar restriction should be applied to EPA File Symbol 74843-E. The garments sold under this registration number should be limited to outerwear (such as shirts, trousers, jackets etc.) only and not include tight-fitting clothing items or undergarments that would come into close contact with the skin (such as intimate apparel, underwear, bathing suits, hats or caps).
4. As the registrant's representative has stated that children under the age of 5 will not wear treated garments, a condition of this registration should be that treated (registered) garments will not include clothing for children of under this age.
5. This registration should be limited to clothing. It should not include items such as sheets, blankets, or sleeping bags.
6. For the purposes of this action, TRB has examined the formulations and labels for the products registered under EPA Reg. Nos. 4816-696 and 48139-11 and compared these with the application under EPA File Symbol 74843-E and has determined there is an adequate similarity. This action does not address the adequacy and/or acceptability of any acute toxicity data which may have been submitted for the two cited products.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

26/February/2003

MEMORANDUM

Subject: EPA Reg. No. /File Symbol: 74843-E Buzz Off Insect Shield Apparel  
DP Barcode: D285609  
Case No: 067402  
PC Code: 109701 Permethrin, mixed cis,trans (ANSI)

From: John C. Redden, Team Leader /s/ JCR  
Technical Review Branch  
Registration Division (7505C)

To: Susan Stanton, PM Team 03  
Insecticide Branch  
Registration Division (7505C)

Applicant: Buzz Off Insect Shield, LLC  
701 Green Valley Road, Suite 302  
Greensboro, NC 27408

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Permethrin.....	0.52%
<u>Inert Ingredient(s):</u> .....	<u>99.48%</u>
Total:	100.00%

ACTION REQUESTED:



The Product Manager requests:

"On behalf of the Buzz Off Insect Shield, LLC, ChemReg International has submitted an application to register clothing treated with permethrin to repel insects. Registration of the treated clothing is necessary, since the product does not meet the criteria for exemption as a treated article. In support of this application the company has submitted requests for waivers of all acute toxicity data. Please review the waiver requests and determine whether they may be granted. The permethrin product that will be used to treat the clothing is also pending registration (74843-R)."

## BACKGROUND

The Registrant, in a letter dated 9/4/2002, is claiming that their product is substantially similar to registered products. This registration would be for clothing impregnated with permethrin at 0.52% for; "...repelling mosquitoes, ticks, ants, fleas, flies, chiggers, and mites."

The Registrant states:

"With the increasing concerns over mosquito- or tick-vectored diseases such as West Nile Virus and Lyme disease, the availability of clothing properly treated with an effective repellent, particularly when used in combination with a skin-applied repellent, could provide cost effective and consistent personal protection compared to currently available approaches. The increased incidence and concerns over insect-vectored diseases is well known. Treatment of clothing with permethrin is one of the approaches recommended by the World Health Organization, as well as by EPA and the Centers for Disease Control."

Later the Registrant states that this product is Toxicity Category IV, and that no signal word, first aid statements or human hazard precautionary statements be required. The Registrant also states:

"As this product is expected to be handled by children, albeit not worn by children under age 5, we do not believe that it appropriate to include the "keep out of reach of children" statement on the labeling."

The Registrant is submitting this action as a "me-too" application and is requesting expedited review. For a "me-too" application, it is required that a registered product be cited.

The Registrant submitted a request for waiver of the acute toxicity data. In that waiver request the Registrant states that EPA File Symbol 74843-E is probably similar to EPA Reg. No. 71012-1. TRB does not recommend the waiver of the acute toxicity data as actual data is available to support this registration.

## RECOMMENDATIONS

TRB has determined that EPA File Symbol 74843-R is substantially similar to EPA Reg. No. 71012-1. TRB requests that the PM address data compensation issues with the Registrant.

TRB generated the following acute toxicity profile for EPA File Symbol 74843-R.

Guideline No.	Study Type	Cited Product	Toxicity Category; Core Grade
81-1	Acute Oral	71012-1	III
81-2	Acute Dermal	71012-1	III
81-3	Acute Inhalation	71012-1	IV
81-4	Primary Eye Irritation	71012-1	IV
81-5	Primary Skin Irritation	71012-1	IV
81-6	Dermal Sensitization	71012-1	Non-sensitizer

## LABELING

**PRODUCT ID #:** 074843-00002

**PRODUCT NAME:** Buzz Off Insect Shield Apparel

### PRECAUTIONARY STATEMENTS

**SIGNAL WORD:** CAUTION

### Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if swallowed. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

### First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Label Created by: John Redden on 02/26/2003 Last Updated by: John Redden on 02/26/2003

# Fee for Service

This package includes the following:

☐ New FFS Action

☐ Amendment

☒ Waiver Request

☒ Voluntary Payment Request

for Division

☒ RD

☐ AD

☐ BPPD

Receipt Nos. S-

Product/Risk Manager:

13

EPA File Symbol/Reg. No.

81041-R

Pin-Punch Date:

6/3/04

☐ This item is NOT subject to FFS action.

Action Code: R30

Amount Due: \$ 1000

Voluntary Payment Reduction Amount:

☐ 0%

☐ 40%

☐ 80%

Original Decision #:

☐ 10%

☐ 50%

☐ 90%

☐ 20%

☐ 60%

☐ 100%

☐ 25%

☐ 70%

☐ Other

D- 340273

☐ 30%

☐ 75%

\_\_\_\_\_%

Reviewer: Livsh

Date: 6/12/04

Remarks:

JB Waiver request

**Health & Environmental Horizons, Ltd**

2851 South Haven Road  
Annapolis, MD 21401  
410-721-7689/301-261-3114 (phone/fax)

June 1, 2004

US Environmental Protection Agency  
Registration Division (7504C)  
VolPay/Linda Arrington  
Ariel Rios Building  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

SUBJECT: PRIA VOL PAY; SMALL BUSINESS WAIVER REQUEST for FEES;  
EPA Registration Number 81041-R

Dear Linda;

I request a fee for service for a small business and under the criteria listed in the Pesticide Registration Improvement Act of 2003 request a full waiver of all fees.

Certification for Small Business:

Section 1. Business Identification

Bikel Company, Ltd.  
Sudo Building 3 rd Floor  
160-18 Samsung-Dong, Kangnam-Ku  
Seoul, Korea

EPA Company Number: 81041

Contact: R. Bruce Jaeger (US Agent)  
410-721-7689 (phone)  
301-261-3114 (fax)  
[bjja9876543@AOL.com](mailto:bjja9876543@AOL.com) (e:mail)

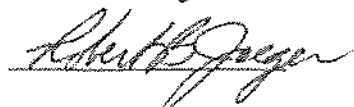
Section 2. Small Business Certification

Number of affiliates: None  
Global Gross Revenue from Pesticides: Zero  
Number of Employees: 311

### Section 3. Certification Statement

I, Robert B. Jaeger, President of Health & Environmental Horizons, Ltd, agent for Bikel Company, Ltd., am authorized and have personal knowledge sufficient to make this certification on Behalf of Bikel Company, Ltd. I hereby certify under penalty of perjury that the documentation submitted in connection with Bikel Company's Waiver/Full Fee Reduction request is true, complete, and correct in all material respects.

Robert B. Jaeger



President, Health & Environmental Horizons, Ltd.

May 31, 2004

### Section 4. Documentation

No Pesticide Maintenance Fees have been paid because the EPA Registration Request is for a new pesticide and is not yet registered with EPA. The EPA Registration Number is 81041-R.

The management and ownership of Bikel Company had no previous control over any entity with gross global revenues from pesticide sales in the prior 3-year period. It is a newly formed start-up company.

A copy of the company structure for Bikel Company, Inc. is attached.

### Section 5. Summary

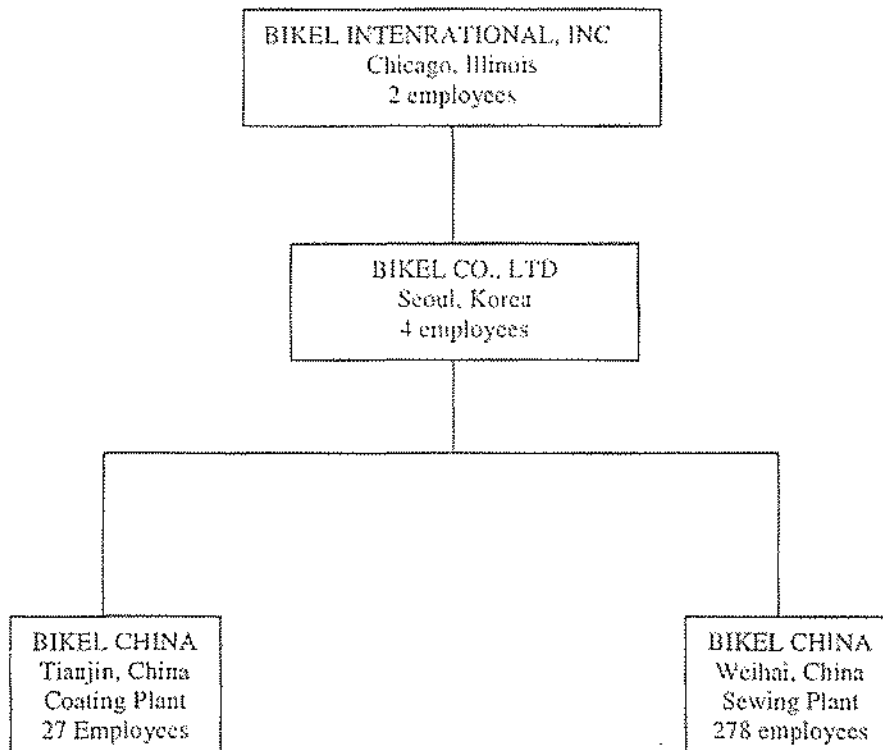
Bikel Company, Ltd. qualifies under the provisions of PRIA for a 100% reduction in the Small Business Waiver of Fee for Service. It has less than 500 employees (i.e. 311) and has less than \$10 Million (i.e. \$"0") in pesticide revenues.

Sincerely,



Robert B. Jaeger  
President

COMPANY STRUCTURE  
BIKEL INTERNATIONAL, INC.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

June 17, 2004

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-340273  
EPA File Symbol or Registration Number: 81041-R  
Product Name: EXPEL  
EPA Receipt Date: 19-Feb-2004  
EPA Company Number: 81041  
Company Name: BIKEL COMPANY, LTD.

R. BRUCE JAEGER  
HEALTH & ENVIRONMENTAL HORIZONS, LTD.  
BIKEL COMPANY, LTD.  
2851 SOUTH HAVEN ROAD  
ANNAPOLIS, MD 21401-

SUBJECT: Receipt of Registration Service Fee Voluntary Payment Notice and Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your Notice of Intent to Submit Voluntary Payment for the action described below.

The Action has been identified as Action Code: R30

NEW PRODUCT; ME-TOO PRODUCT FAST TRACK;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If the determination indicates that payment is due, you will receive instructions for submitting payment at that time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 305-6249.

Sincerely,

Front End Processing Staff  
Information Resources and Services Division



58



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

June 8, 2004

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

HEALTH & ENVIRONMENTAL HORIZONS, LTD.  
BIKEL COMPANY, LTD.  
2851 SOUTH HAVEN ROAD  
ANNAPOLIS, MD 21401-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 07-JUN-04. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Health & Environmental Horizons, Ltd  
2851 South Haven Road  
Annapolis, MD 21401  
301-261-3114 (phone/fax)

## FAX

DATE: April 28, 2004

TO: George LaRocca, PM13  
Insecticide Branch (7505C)  
EPA

FAX NO: 703-305-6596

FROM: Bruce Jaeger

MESSAGE: I have attached copies of a previous submission dated March 4, 2004, wherein I submitted the appropriate EPA Form 8570-34 (as listed in PRN 98-5). The data matrix, EPA Form 8570-35 is attached to this fax and was not previously submitted. However, one comment that I have is the fact that this product is nothing more than the end use of EPA Registration Number [REDACTED] a manufacturing use product. There is nothing unique at all about this product since it is simply taking a registered product and using it as approved on the [REDACTED] label. The relevant dermal exposure data and studies are referenced in previous submissions. I do note that Buzz Off Insect Shield did not provide data except for efficacy and "other", indicated in the data submitters list. I believe our submission is now complete and that all relevant data for this product reside in the data base supporting EPA Reg. [REDACTED] and relevant dermal exposure scenarios supporting EPA Reg. No. 74843-1 and -2 are cited by reference to documents available under FOIA, and have been cited in our submission.

As always I appreciate your phone calls to let me know what is happening. Hopefully this will resolve your concerns. Thanks for your help.

Regards,

  
Bruce Jaeger

Attached copy of March 4 submission (date stamped March 5) and EPA Form 8570-35

\*Product ingredient source information may be entitled to confidential treatment\*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

May 27, 2004

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

HEALTH & ENVIRONMENTAL HORIZONS, LTD.  
BIKEL COMPANY, LTD.  
2851 SOUTH HAVEN ROAD  
ANNAPOLIS, MD 21401

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 31-MAR-04. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected Study [01].

- \* You failed to provide the Confidential Data in the Confidential attachment.

Health & Environmental Horizons, Ltd.  
2851 South Haven Rd.  
Annapolis, MD 21401  
Phone 410-721-7689  
Fax 301-261-3114

March 22, 2004

George T. LaRocca (PM 13)  
Insecticide Branch/Registration Division (7505C)  
Office of Pesticide Programs  
Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Ave., NW  
Washington, DC 20460

Dear George:

SUBJECT: EPA Registration No. 81041-R; Resubmission of Document Number 4 in  
Response to EPA Letter March 8, 2004, same subject.

I received your letter regarding the confidentiality claim for Document Number 4 in EPA  
Registration Request Number 81041-R. Based upon your comments I have revised  
Document Number 4 and removed all claims of confidentiality. Hopefully you will now  
find it meets the standards of PR Notice 86-5 and we can move ahead with considering our  
request for registration. Thanks for your assistance.

Sincerely,

  
R. Bruce Jaeger  
President

VOLUME 1 OF 2 OF SUBMISSION  
TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF APPLICANT/SUBMITTER:

Bikel Company, Ltd  
Sudo Building 3<sup>rd</sup> Floor, 160-18 Samsung-Dong  
Kangnam-Ku, Seoul, Korea

U.S. AGENT/REPRESENTATIVE:

R. Bruce Jaeger  
President  
Health & Environmental Horizons, Ltd.  
2851 South Haven Rd.  
Annapolis, MD 21401

REGULATORY ACTION:

Submission of Me-Too Registration Request for Expel .

TRANSMITTAL DATE:

March 22, 2004

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE Number
462084-00	1 of 2	Transmittal Document	-
46208401	2 of 2	Document Number 1: Product Identification and Disclosure of Ingredients	151-10 830.1100
46208402	2 of 2	Document Number 2: Description of Beginning Materials and Manufacturing Process	151-11 830.1200

46208403	2 of 2	Document Number 3: Discussion of the Formation of Impurities	151-12 830.1400
	2 of 2	Document Number 4: Certified Limits (Resubmission)	158.175 830.1750

COMPANY OFFICIAL: R. Bruce Jaeger

Signature: 

COMPANY NAME: Bikel Company, Ltd.

COMPANY CONTACT: R. Bruce Jaeger

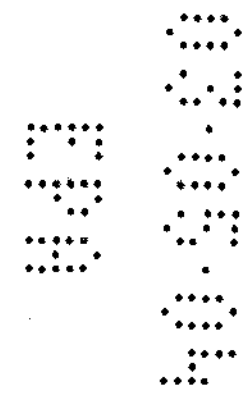
AGENT/REPRESENTATIVE: R. Bruce Jaeger

PM 13  
3/9/04

Health & Environmental Horizons, Ltd.  
2851 South Haven Rd.  
Annapolis, MD 21401  
Phone 410-721-7689  
Fax 301-261-3114

March 4, 2004

George T. LaRocca (PM 13)  
Insecticide Branch/Registration Division (7505C)  
Office of Pesticide Programs  
Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Ave., NW  
Washington, DC 20460



Dear George;

SUBJECT: Application for a Me-Too Registration for Expel, a Treated Article Product  
Containing the Currently Registered Active Ingredient, Permethrin.  
EPA Registration No. 81041-R

First, thanks for the phone calls and information you provided to me. I greatly appreciate your help.

I have attached the two forms you indicated you needed: (1) EPA Form 8570-27, Formulator's Exemption Statement, and (2) EPA Form 8570-34, General Offer to Pay.

You should also be aware that the registrant intends to treat the material and then make the article from that treated material, whether it is a car tarp, tent, pet blanket, or backpack. They will manufacture all of their own end-use items in their manufacturing facility in Seoul, Korea. Please let me know whether they need a distributor's license, and the process to obtain such a license.

They will attach a tag to the treated fabric after it has been treated with [REDACTED] indicating that it has been treated with a registered pesticide product. That information will remain with the treated fabric until it is manufactured into an end-use item, such as a backpack, hunting blind, awning, truck cover, outerwear garment, and other items identified on the label. A tag will be permanently attached to the manufactured item after it has been assembled and it will remain with that item during distribution and sale. The information on these tags has already been submitted to EPA.

If you have any additional questions or concerns please do not hesitate to contact me. Considering the nature of this registration request we would appreciate as quick a turn-around as possible. Once again, thanks for your assistance.

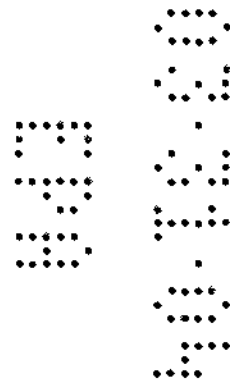
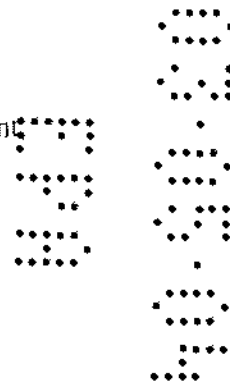
\*Product ingredient source information may be entitled to confidential treatment\*



Sincerely,

  
Robert B. Jaeger  
President

Attachments: (1) EPA Form 8570-27, Formulator's Exemption Statement  
(2) EPA Form 8570-34, General Offer to Pay



United States

Washington, DC 20460

(40 CFR 152.85)

Applicant's Name and Address

Bikel Company, Ltd.  
Sudo Building 3rd Floor, 160-18 Samsung-Dong  
Kangnam, Seoul, Korea

EPA File Symbol/Registration Number

A1041-B

Product Name

Exped

Date of Confidential Statement of Formula **EPA Form 8570-4)**

210304

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):

## Permian

- (2) Of these, each active ingredient listed in paragraph 14) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

- (3) Indicate by checking (A) or (B) below which paragraph applies:

- ☐ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- ☒ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

### Source

### Active ingredient

Product Name

\*\*\* Registration Number

## Permethrin

Signature \_\_\_\_\_

Name and Title

Robert B. Jaeger, President, H&EH, Ltd

Date \_\_\_\_\_



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.  
Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Bikei Company, Ltd./ Sudo Building, 160-18 Sanjungs-Dong, Kanganm, Seoul/773-817-1322	EPA Registration Number/File Symbol 81041-R
Active Ingredient(s) and/or representative test compound(s) Permethrin	Date 3/4/04
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Noncrop, wide area, and general indoor/outdoor treatments/ pets and domestic animals outdoor	Product Name Expel

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☒ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of the product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

3/4/04

Typed or Printed Name and Title

Robert B. Jaeger, President, H&EH, Ltd.

[illegible]

\*Product ingredient source information may be entitled to confidential treatment\*

[illegible]



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

March 8, 2004

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

HEALTH & ENVIRONMENTAL HORIZONS, LTD.  
BIKEL COMPANY, LTD.  
2851 SOUTH HAVEN ROAD  
ANNAPOLIS, MD 21401-

Report of Analysis for Compliance with PR Notice 86-5

SUBJECT: EXPTEL - EPA Registration Number 81041-R

Thank you for your submittal of 19-FEB-04. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

Rejected Study [04]:

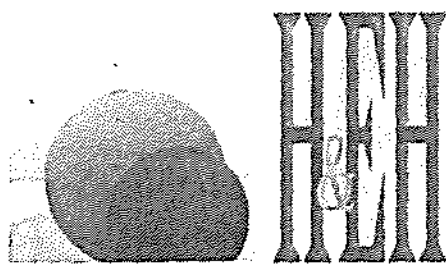
\* FIFRA Section 10(d)(1) only provides for confidentiality of information which: (A) discloses manufacturing or quality control processes, (B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or (C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide... Since your claim covers information entirely outside this narrow range of subject matter, it cannot be accepted.

Sincerely yours,

George T. LaRocca  
Product Manager 13  
Insecticide Branch

Registration Division 7505C

462084-00



HEALTH & ENVIRONMENTAL HORIZONS, LTD

2851 South Haven Road  
Annapolis, MD 21401  
301-261-3114 PHONE/FAX

February 17, 2004

George T. LaRocca (PM 13)  
Insecticide Branch/Registration Division (7505C)  
Office of Pesticide Programs  
Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Ave., NW  
Washington, DC 20460

Dear George;

SUBJECT: Application for a Me-Too Registration for Expel, a Treated Article Product  
Containing the Currently Registered Active Ingredient, Permethrin.  
EPA Registration No. 81041-R

On behalf of Bikel Company, Ltd., Health & Environmental Horizons, Ltd hereby submits a request for registration of a treated article product. The product is fabric, cloth and clothing material that has been treated with [REDACTED] a registered EPA product containing the active ingredient Permethrin. The name of the product is Expel.

#### Description of Product

Expel is fabric and other clothing materials that have been specifically treated with [REDACTED] to give the fabric and the articles made from it specific insect repellent properties. The repellent properties are exactly as demonstrated for other permethrin products containing 0.52% w/w permethrin as active ingredient.

#### Proposed Uses

A Me-Too Registration for Expel (Insect repellent fabric/apparel), containing permethrin, is being proposed for the use of the treated fabric in the manufacture of articles such as netting, tents, shelters, awnings, truck covers, hunting blinds, backpacks, sleeping bag shells; in outerwear garments (such as coats, jackets, coveralls, gaiters, chaps, hat bands, bibs and hunting vests), and for domestic animal care products (such as pet bedding, blankets, rugs, netting and kennel/stall coverings). The articles made from Expel treated fabric will provide insecticidal and/or repellent properties against ticks, mosquitoes, spiders, ants, fleas, flies,

and other flying and crawling insects. Expel is made using [REDACTED] following current EPA label directions for use [REDACTED]. Expel is substantially similar to, if not identical to, other currently registered treated article products such as EPA Reg. No. 74843-2, Buzz Off Insect Shield Apparel.

#### Documents Submitted in Support of the Subject Application

The data and information in the existing files for permethrin products, such as EPA Reg. No. [REDACTED], EPA Reg. No. [REDACTED] and EPA Reg. No. 74843-2 should be used and referred to as necessary for support of this application. Also, five (5) copies of the proposed labeling, three (3) copies of supporting data and one (1) copy each of the following are attached for Expel:

- o Application for Pesticide Registration (Form 8570-1)
- o Confidential Statement of Formula (Form 8570-4, Document Number 1 Confidential Attachment)
- o Manufacturing Process for Expel (Document Number 2, Confidential Attachment)
- o Certification with Respect to Citation of Data (Form 8570-34)
- o Data Matrix (EPA Form 8570-35)
- o Transmittal Document for Expel

#### Request for Waivers of Product Chemistry, Environmental Fate and Ecological Effects Data Requirements

Bikel Company, Ltd. requests a waiver for all product chemistry, environmental fate and ecological effects data for Expel. Expel is a treated article product and a "pesticide" product only because it has been treated with a registered insecticide, permethrin. The fabrics that have been treated in accordance with the label directions for use for EPA Reg. No. [REDACTED] are called Expel. They have been given specific insecticidal and repellent properties resulting directly from the use of [REDACTED] in the manufacturing process, a use that is already authorized on the [REDACTED] label. The insecticidal/repellent properties will last for 25 washings, providing the article has not been dry cleaned. Many insects that come in direct contact with Expel fabric may be killed, others may be repelled. Thus, in accordance with 40 CFR part 152.3 the definition of a "pesticide" and "pesticide product" requires that "treated articles" containing pesticide properties be registered. However, there is nothing unique about the treated articles that are produced in accordance with the label directions for use for EPA Reg. No. [REDACTED]. The insecticidal properties related to such an article are directly related to the active ingredient, permethrin, that has been impregnated in the fibers and coating of the cloth fabrics. Therefore, any and all data that have been used in



support of EPA Reg. No. [REDACTED] or for permethrin itself, should be used to support Expel. Expel has no unique product chemistry properties and none of the product chemistry data requirements for formulated end-use products are relevant to treated articles, such as Expel. There is no EPA testing guideline available for testing such treated articles and therefore, these requirements should be waived. Furthermore, a review of the 40 CFR 158.190 listed physical and chemical characteristics data requirements for EP (End-Use Products), such as Expel, indicates they are not required "if their active ingredient is purchased from a registered source". The source in this case is EPA Reg. No. [REDACTED]. Finally, many of these are "conditional" based upon a determination of properties outlined in footnotes 4 and 6-10, and involve such characteristics as "dispersible with water, contains combustible liquids, is potentially explosive, is a liquid", and so forth. These are not properties of treated fabrics. The rationale for waiving any environmental fate and ecological effects data is identical to the waiver request for product chemistry data requirements in that they do not meet the intent of 158.290 and 158.490 and therefore should be waived as well. EPA has granted waivers for other treated article products containing permethrin that have the same intended use patterns. This request is consistent with decisions previously made by EPA for permethrin, and permethrin treated articles.

#### Request for Waivers of Toxicology Data Requirements

Expel is a fabric product containing 0.52% permethrin. The concentration of permethrin in/or fabric is based upon the use directions for [REDACTED]. Specific registered use directions for [REDACTED] are followed exclusively for producing Expel. Accordingly, any data and/or decisions that support those treated article products similarly support Expel. Any additional toxicity studies would be redundant and a waste of valuable animal resources, manpower, and unnecessary expense. Furthermore, none of the Expel fabric will be manufactured into clothing apparel that will come into intimate contact with human skin. The treated fabric products are outerwear apparel, back packs, hunting vests, tents and other items listed on the label that have no dermal exposure component. Finally, the US Military has already performed extensive testing for military issue socks, boots, and other apparel designed to be worn in close contact with human skin. The US EPA has cleared these uses. Documents listed in the attachment identify the supporting documents and decisions that justify the safe use of treated permethrin fabrics when used in accordance with registered directions for use. Therefore, all toxicology data requirements should be waived.

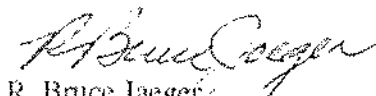
#### Conclusion

The only relevant toxicological data requirements for Expel are dermal irritation, sensitization and repeated dermal contact studies. The sensitization and irritation properties for treated fabrics are directly related to the chemical active ingredient that has been impregnated or coated in/on each fabric and not to any article of clothing or fabric (where applicable) that has been manufactured from it. Such properties have already been evaluated for permethrin and for permethrin and should be waived for treated articles. No additional pesticide related chemical materials have been introduced, and therefore any irritant or sensitizing properties have already been examined and cleared by EPA. The only other material that has been introduced is the fabric itself and there is no existing or relevant

toxicology test for evaluating "fabric". The continuous or repeated wearing of treated apparel has been evaluated by the US Military and data supporting its use in treated articles of military clothing similarly support the use of Expel. Any additional testing of Expel would be redundant and should be waived. Expel treated fabrics that are made into tents, backpacks, shelters, and similar articles do not share a similar concern for repeated close contact with wearing apparel that is in direct contact with skin, and therefore should also be waived. The active ingredient, permethrin, is currently registered in products for use as insecticides and repellents in other treated articles and any data supporting such use similarly support the registration of Expel. No additional toxicological data are necessary to demonstrate the safety of such treated articles for use by humans and domestic animals.

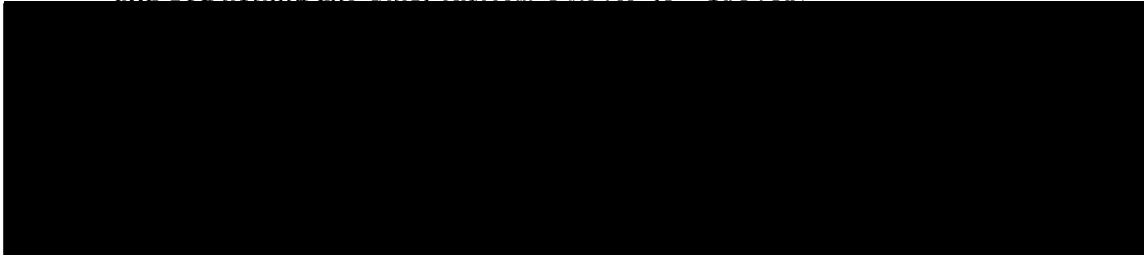
We respectfully request you give this registration full consideration. Please contact me directly if you have any questions, comments or requests for additional information regarding this application.

Sincerely,

  
R. Bruce Jaeger  
President

Attachment: List of supporting EPA documents for treated article use

Attachment: List of supporting EPA documents for treated article use for Permethrin, chemical code 109701:

- (1) July 31, 1989. Memorandum. 4 pages. Curt Lunchick. Non-dietary Exposure Branch. Registration of Permethrin for Military Use. HED Project #9-1356.
- (2) Undated. Review. 3 pages. Registration Division. RD Risk Assessment - Astex Mattress Cover. EPA File Symbol 71012-R.
- (3) Undated. Memorandum. 4 pages. George Tompkins. Special Review & Reregistration Division. [Reviews studies dated 1994] Review Three Exposure Assessments for Permethrin. EPA Reg. No.: 279-3051, 3083, 3014, 3059. MRIDs 43342601, 43324801, 43355501.
- (4) November 21, 1989. Memorandum. 24 pages. Edwin Budd. Toxicology Branch. EPA Reg. Nos. 50404-L and 50404-A. Permethrin Arthropod Repellent (50404-L) for Use on Military Uniforms and Fabrics and Coulston's Permanone Tick Repellent...Tox Review 007624.
- (5) July 27, 1990. Memorandum. 16 pages. Roger Gardner. Toxicology Branch I. Permanone (Permethrin) Tick-Repellent Dermal Absorption Data. Tox Review 008012. Attachment following:  
June 20, 1990. Memorandum. John Doherty. Toxicology Branch I. EPA Id#63120-R, -E, and -G. Permethrin: Request from the military for the registration of three products for use on battle dress uniforms and clothing and bed netting and other fabrics. Tox Review 008012.
- (6) 
- (7) June 5, 1995. DER. 5 Pages. John Doherty. Toxicology Branch I. "Permethrin: Skin Sensitization Study". MRID No. 410311-06. Tox Review No. 011574.
- (8) June 13, 1995. Memorandum. 21 pages. John Doherty. Toxicology Branch I. EPA Id No. 109701. Permethrin: Review of a series 81-6 dermal sensitization study (guinea pig maximization test) and a series 85-2 dermal penetration study. Tox review 011574. MRID 41831106, 43169001.
- (9) April 29, 1996. Memorandum. 3 pages. Carol Glasgow. Registration Support Branch, RD. EPA File Symbol 4816-688 Permanone Multi-Purpose 10% E.C. reevaluation of tox category, primary dermal irritation. MRID 43895001.
- (10) February 22, 2001. Memorandum. 11 pages. Steven Weiss. Registration Action Branch HED. Review of Permethrin Rub-Off Trial from Astex Mattress Liners. MRID #45256001.
- (11) April 26, 2001. Review. 3 pages. Vern McFarland. Insecticide Branch. Efficacy Review of Unicorn .50% Permethrin: Provide references in support of me-too registration of a new product containing an old chemical on the basis of the cite-all method.

46208403	2 of 2	Document Number 3: Discussion of the Formation of Impurities	151-12 830.1400
Reject (04)	2 of 2	Document Number 4: Certified Limits	158.175 830.1750

COMPANY OFFICIAL: R. Bruce Jaeger

Signature: 

COMPANY NAME: Bikel Company, Ltd..

COMPANY CONTACT: R. Bruce Jaeger

AGENT/REPRESENTATIVE: R. Bruce Jaeger

Page 2 of 2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

February 20, 2004

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

R. BRUCE JAEGER  
HEALTH & ENVIRONMENTAL HORIZONS, LTD.  
BIKEL COMPANY, LTD.  
2851 SOUTH HAVEN ROAD  
ANNAPOLIS, MD 21401-

PRODUCT NAME: EXPEL  
COMPANY NAME: BIKEL COMPANY, LTD.  
OPP IDENTIFICATION NUMBER: 262232  
EPA FILE SYMBOL: 81041-R  
EPA RECEIPT DATE: 02/19/04

SUBJECT: RECEIPT OF APPLICATION FOR A NEW ME-TOO REGISTRATION

DEAR REGISTRANT:

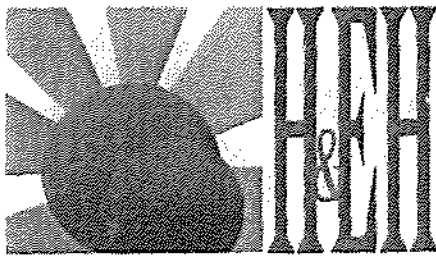
The Office of Pesticide Programs has received your application for a new 'me-too' registration and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 13, at (703) 305-6100.

Sincerely,

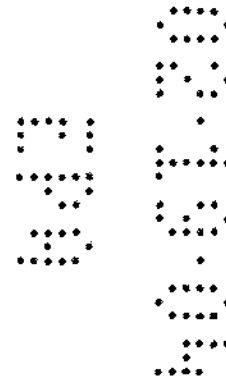
*Patricia A. Moore*  
Front End Processing Staff  
Information Services Branch  
Information Resources and Services Division



## HEALTH & ENVIRONMENTAL HORIZONS, LTD

2851 South Haven Road  
Annapolis, MD 21401  
301-261-8491 PHONE/FAX

COPY



February 17, 2004

George T. LaRocca (PM 13)  
Insecticide Branch/Registration Division (7505C)  
Office of Pesticide Programs  
Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Ave., NW  
Washington, DC 20460

Dear George;

SUBJECT: Application for a Me-Too Registration for Expel, a Treated Article Product  
Containing the Currently Registered Active Ingredient, Permethrin.  
EPA Registration No. 81041-R

On behalf of Bikel Company, Ltd., Health & Environmental Horizons, Ltd hereby submits a request for registration of a treated article product. The product is fabric, cloth and clothing material that has been treated with [REDACTED] a registered EPA product containing the active ingredient Permethrin. The name of the product is Expel.

### Description of Product

Expel is fabric and other clothing materials that have been specifically treated with [REDACTED] to give the fabric and the articles made from it specific insect repellent properties. The repellent properties are exactly as demonstrated for other permethrin products containing 0.52% w/w permethrin as active ingredient.

### Proposed Uses

A Me-Too Registration for Expel (Insect repellent fabric/apparel), containing permethrin, is being proposed for the use of the treated fabric in the manufacture of articles such as netting, tents, shelters, awnings, truck covers, hunting blinds, backpacks, sleeping bag shells; in outerwear garments (such as coats, jackets, coveralls, gaiters, chaps, hat bands, bibs and hunting vests), and for domestic animal care products (such as pet bedding, blankets, rugs, netting and kennel/stall coverings). The articles made from Expel treated fabric will provide insecticidal and/or repellent properties against ticks, mosquitoes, spiders, ants, fleas, flies,

\*Product ingredient source information may be entitled to confidential treatment\*

and other flying and crawling insects. Expel is made using [REDACTED] following current EPA label directions for use (EPA Reg. No. [REDACTED]). Expel is substantially similar to, if not identical to, other currently registered treated article products such as EPA Reg. No. 74843-2, Buzz Off Insect Shield Apparel.

#### Documents Submitted in Support of the Subject Application

The data and information in the existing files for permethrin products, such as EPA Reg. No. [REDACTED], EPA Reg. No. [REDACTED] and EPA Reg. No. 74843-2 should be used and referred to as necessary for support of this application. Also, five (5) copies of the proposed labeling, three (3) copies of supporting data and one (1) copy each of the following are attached for Expel:

- o Application for Pesticide Registration (Form 8570-1)
- o Confidential Statement of Formula (Form 8570-4, Document Number 1, Confidential Attachment)
- o Manufacturing Process for Expel (Document Number 2, Confidential Attachment)
- o Certification with Respect to Citation of Data (Form 8570-34)
- o Data Matrix (EPA Form 8570-35)
- o Transmittal Document for Expel

#### Request for Waivers of Product Chemistry, Environmental Fate and Ecological Effects Data Requirements

Bikel Company, Ltd. requests a waiver for all product chemistry, environmental fate and ecological effects data for Expel. Expel is a treated article product and a "pesticide" product only because it has been treated with a registered insecticide, permethrin. The fabrics that have been treated in accordance with the label directions for use for EPA Reg. No. [REDACTED] are called Expel. They have been given specific insecticidal and repellent properties resulting directly from the use of [REDACTED] in the manufacturing process, a use that is already authorized on the [REDACTED] label. The insecticidal/repellent properties will last for 25 washings, providing the article has not been dry cleaned. Many insects that come in direct contact with Expel fabric may be killed, others may be repelled. Thus, in accordance with 40 CFR part 152.3 the definition of a "pesticide" and "pesticide product" requires that "treated articles" containing pesticide properties be registered. However, there is nothing unique about the treated articles that are produced in accordance with the label directions for use for EPA Reg. No. [REDACTED]. The insecticidal properties related to such an article are directly related to the active ingredient, permethrin, that has been impregnated in the fibers and coating of the cloth fabrics. Therefore, any and all data that have been used in

support of EPA Reg. No. [REDACTED] or for permethrin itself, should be used to support Expel. Expel has no unique product chemistry properties and none of the product chemistry data requirements for formulated end-use products are relevant to treated articles, such as Expel. There is no EPA testing guideline available for testing such treated articles and therefore, these requirements should be waived. Furthermore, a review of the 40 CFR 158.190 listed physical and chemical characteristics data requirements for EP (End-Use Products), such as Expel, indicates they are not required "if their active ingredient is purchased from a registered source". The source in this case is EPA Reg. No. [REDACTED]. Finally, many of these are "conditional" based upon a determination of properties outlined in footnotes 4 and 6-10, and involve such characteristics as "dispersible with water, contains combustible liquids, is potentially explosive, is a liquid", and so forth. These are not properties of treated fabrics. The rationale for waiving any environmental fate and ecological effects data is identical to the waiver request for product chemistry data requirements in that they do not meet the intent of 158.290 and 158.490 and therefore should be waived as well. EPA has granted waivers for other treated article products containing permethrin that have the same intended use patterns. This request is consistent with decisions previously made by EPA for permethrin, and permethrin treated articles.

#### Request for Waivers of Toxicology Data Requirements

Expel is a fabric product containing 0.52% permethrin. The concentration of permethrin in/or fabric is based upon the use directions for [REDACTED]. Specific registered use directions for [REDACTED] are followed exclusively for producing Expel. Accordingly, any data and/or decisions that support those treated article products similarly support Expel. Any additional toxicity studies would be redundant and a waste of valuable animal resources, manpower, and unnecessary expense. Furthermore, none of the Expel fabric will be manufactured into clothing apparel that will come into intimate contact with human skin. The treated fabric products are outerwear apparel, back packs, hunting vests, tents and other items listed on the label that have no dermal exposure component. Finally, the US Military has already performed extensive testing for military issue socks, boots, and other apparel designed to be worn in close contact with human skin. The US EPA has cleared these uses. Documents listed in the attachment identify the supporting documents and decisions that justify the safe use of treated permethrin fabrics when used in accordance with registered directions for use. Therefore, all toxicology data requirements should be waived.

#### Conclusion

The only relevant toxicological data requirements for Expel are dermal irritation, sensitization and repeated dermal contact studies. The sensitization and irritation properties for treated fabrics are directly related to the chemical active ingredient that has been impregnated or coated in/on each fabric and not to any article of clothing or fabric (where applicable) that has been manufactured from it. Such properties have already been evaluated for permethrin and for [REDACTED] and should be waived for treated articles. No additional pesticide related chemical materials have been introduced, and therefore any irritant or sensitizing properties have already been examined and cleared by EPA. The only other material that has been introduced is the fabric itself and there is no existing or relevant



toxicology test for evaluating "fabric". The continuous or repeated wearing of treated apparel has been evaluated by the US Military and data supporting its use in treated articles of military clothing similarly support the use of Expel. Any additional testing of Expel would be redundant and should be waived. Expel treated fabrics that are made into tents, backpacks, shelters, and similar articles do not share a similar concern for repeated close contact with wearing apparel that is in direct contact with skin, and therefore should also be waived. The active ingredient, permethrin, is currently registered in products for use as insecticides and repellents in other treated articles and any data supporting such use similarly support the registration of Expel. No additional toxicological data are necessary to demonstrate the safety of such treated articles for use by humans and domestic animals.


We respectfully request you give this registration full consideration. Please contact me directly if you have any questions, comments or requests for additional information regarding this application.

Sincerely,

  
R. Bruce Jaeger  
President

Attachment: List of supporting EPA documents for treated article use

Attachment: List of supporting EPA documents for treated article use for Permethrin, chemical code 109701:

- (1) July 31, 1989. Memorandum. 4 pages. Curt Lunchick. Non-dietary Exposure Branch. Registration of Permethrin for Military Use. HED Project #9-1356.
- (2) Undated. Review. 3 pages. Registration Division. RD Risk Assessment – Astex Mattress Cover. EPA File Symbol 71012-R.
- (3) Undated. Memorandum. 4 pages. George Tompkins. Special Review & Reregistration Division. [Reviews studies dated 1994] Review Three Exposure Assessments for Permethrin. EPA Reg. No.: 279-3051, 3083, 3014, 3059. MRIDs 43342601, 43324801, 43355501.
- (4) November 21, 1989. Memorandum. 24 pages. Edwin Budd. Toxicology Branch. EPA Reg. Nos. 50404-L and 50404-A. Permethrin Arthropod Repellent (50404-L) for Use on Military Uniforms and Fabrics and Coulston's Permanone Tick Repellent...Tox Review 007624.
- (5) July 27, 1990. Memorandum. 16 pages. Roger Gardner. Toxicology Branch I. Permanone (Permethrin) Tick-Repellent Dermal Absorption Data. Tox Review 008012. Attachment following:  
June 20, 1990. Memorandum. John Doherty. Toxicology Branch I. EPA Id#63120-R, -E, and -G. Permethrin: Request from the military for the registration of three products for use on battle dress uniforms and clothing and bed netting and other fabrics. Tox Review 008012.
- (6) 
- (7) June 5, 1995. DER. 5 Pages. John Doherty. Toxicology Branch I. "Permethrin: Skin Sensitization Study". MRID No. 410311-06. Tox Review No. 011574.
- (8) June 13, 1995. Memorandum. 21 pages. John Doherty. Toxicology Branch I. EPA Id No. 109701. Permethrin: Review of a series 81-6 dermal sensitization study (guinea pig maximization test) and a series 85-2 dermal penetration study. Tox review 011574. MRID 41831106, 43169001.
- (9) April 29, 1996. Memorandum. 3 pages. Carol Glasgow. Registration Support Branch, RD. EPA File Symbol 4816-688 Permanone Multi-Purpose 10% E.C. reevaluation of tox category, primary dermal irritation. MRID 43895001.
- (10) February 22, 2001. Memorandum. 11 pages. Steven Weiss. Registration Action Branch HED. Review of Permethrin Rub-Off Trial from Astex Mattress Liners. MRID #45256001.
- (11) April 26, 2001. Review. 3 pages. Vern McFarland. Insecticide Branch. Efficacy Review of Unicorn .50% Permethrin; Provide references in support of me-too registration of a new product containing an old chemical on the basis of the cite-all method.

## DATA MATRIX

### TO SUPPORT APPLICATION FOR REGISTRATION OF EXPEL TREATED FABRIC CONTAINING THE REGISTERED ACTIVE INGREDIENT PERMETHRIN

February 17, 2004

#### PRODUCT CHEMISTRY

##### Product Identity and Composition

830.1100	Product Identity and Composition Document 1
830.1200	Description of Starting Materials, Production and Formulation Process Document 2
830.1400	Discussion of Formation of Impurities Document 3
830.1750	Certified Limits Document 4
830.1800	Enforcement and Analytical Method Not Required

##### Physical and Chemical Characteristics

830.6302	Color
830.6303	Physical State
830.6304	Odor
830.7300	Density, bulk density or specific gravity
830.7000	pH

#### PHYSICAL AND CHEMICAL CHARACTERISTICS DATA WAIVER REQUEST. 40CFR 158.190

The following studies are included: All physical and chemical characteristics data identified for EP products.

STUDY TYPE: All physical and chemical characteristics data

ACTIVE INGREDIENT: Permethrin.

REQUESTED BY: Bikel Company, Ltd.,

WAIVER REQUEST JUSTIFICATION: Bikel Company, Ltd. submits this justification

for data waiver from the above listed physical/chemical data requirements. The waiver request is based upon a consideration that the active ingredient used to produce Expel is derived from the application of [REDACTED] a registered source of active ingredient, and a product registered for such use. Furthermore, the data requirements listed in 158.190 for EP products are not relevant to treated articles and are conditional based upon findings listed in the footnotes 4, and 6-10 of the table, 158.190. The request for waiver is consistent with decisions previously made by EPA for permethrin and permethrin treated articles.

#### TOXICOLOGY DATA WAIVER REQUEST, 40CFR 158.340

The following studies are included: All acute toxicity studies, development toxicity studies and genotoxicity studies.

STUDY TYPE: All toxicity data

ACTIVE INGREDIENT: Permethrin.

REQUESTED BY: Bikel Company, Ltd..

SUMMARY: Bikel Company, Ltd. submits this justification for data waiver from the above listed toxicology data requirements. The waiver request is based upon a Cite All request, considering the extensive amount of toxicity data that currently exist for similar permethrin products, all of which share a common mode of toxicity. Any additional testing would be redundant.

#### WAIVER REQUEST JUSTIFICATION:

The waiver request is based upon the following rationales:

US EPA has an extensive file of toxicity data for permethrin products that carry the exact same use pattern and precautionary labeling. Registration for Expel is being sought as a treated article. As such it has unique properties not originally intended to be examined under FIFRA. Treated articles of clothing have been examined for military use for the past 20-30 years. All data relevant to such use and exposure scenarios have been conducted and evaluated by EPA. These uses have been cleared. No additional data are relevant or necessary. There is at least one other substantially similar product or identical product that is currently registered. Thus, exposure to this active ingredient will not be increased.

Permethrin products are common household insecticides, and are formulated in every manner imaginable. Use of a treated article, such as Expel, will not add to the current human exposure that already exists. Rather it will more than likely replace a current product for the same identical use. There are also extensive food uses for permethrin, for which a full battery of toxicology tests are available. All toxicology data requirements should be waived.

ECOLOGICAL EFFECTS DATA WAIVER REQUEST, 40CFR 158.490

850.2100 Avian Acute Oral  
850.2200 Avian Dietary  
850.1075 Freshwater Fish LC50  
850.4250 Freshwater Invertebrate LC50

STUDY TYPE: Avian, aquatic and invertebrate species testing

ACTIVE INGREDIENT: Permethrin.

REQUESTED BY: Bikel Company, Ltd.

SUMMARY: Bikel Company, Ltd. submits this justification for data waiver from the above listed ecological effects data requirements. The waiver request is based upon the rationale that the active ingredient is an existing common use insecticide and repellent product. This product is a manufactured treated fabric and article that will not carry an environmental exposure component. The active ingredient is also not removed from the article by rainfall or other environmental factors, a fact that would ultimately defeat its intended purpose.

WAIVER REQUEST JUSTIFICATION:

Waivers are requested for the above conditional data requirements based on the following rationale:

1. Expel is a treated article with no environmental exposure component.
2. A similar or identical product already exists for which no data were required.
3. The active ingredient is not removed from the treated article by rainfall or other environmental factors, a fact that would ultimately defeat its intended purpose.
4. Data requirements listed at 158.290 and 158.490 are not relevant to the use of Expel, a treated fabric product.

Certification with Respect to Citation of Data

Applicants Name and Address: Bikel Company, Ltd. Sudo Building 3rd Floor, 160-18 Samsung-Dong Kangnam-Ku, Seoul, Korea	EPA File Symbol/Registration Number: #1041-R
	Product Name: Expel
	Date of Application: February 17, 2004

**NOTE:** If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration this is an exclusive use study.

☐ I am the original submitter\*; or

☐ I have obtained the written permission of the original submitter for \_\_\_\_\_, which is

(insert name of chemical)

\_\_\_\_\_ (for multiple chemicals link the companies who are original data submitters

(insert names of companies)

with the appropriate chemical name) to cite that study\*.

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

a. ☐ I am the original data submitter\*; or

☐ I have obtained the written permission of the original data submitter for \_\_\_\_\_, which is

(insert name of chemical)

\_\_\_\_\_ (for multiple chemicals link the companies who are original data submitters

(insert names of companies)

with the appropriate chemical name) to cite that study\*; or

b. ☒ I have notified in writing the companies \_\_\_\_\_ for \_\_\_\_\_ that

(insert names of companies)

(insert name of chemical)

have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

Companies \_\_\_\_\_ for \_\_\_\_\_ (for multiple

(insert names of companies)

(insert name of chemical)

chemicals link the companies who are original data submitters with the appropriate chemical name) listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method\*). (Also, sign the General Offer Statement below.)

Companies \_\_\_\_\_ for \_\_\_\_\_ (for multiple



(insert names of companies)

(insert name of chemical)

chemicals link the companies who are original data submitters with the appropriate chemical name) that have submitted the studies which I have cited (Selective method\*).

4. ☐ I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

\* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature 	Name and Title: R. Bruce Jaeger/President, Health & Environmental Horizons, Ltd.	Date: February 17, 2004
General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.		
Signature 	Name and Title: R. Bruce Jaeger/President, Health & Environmental Horizons, Ltd.	Date: February 17, 2004

VOLUME 1 OF 2 OF SUBMISSION  
TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF APPLICANT/SUBMITTER:

Bikel Company, Ltd  
Sudo Building 3<sup>rd</sup> Floor, 160-18 Samsung-Dong  
Kangnam-Ku, Seoul, Korea

U.S. AGENT/REPRESENTATIVE:

R. Bruce Jaeger  
President  
Health & Environmental Horizons, Ltd.  
2851 South Haven Rd.  
Annapolis, MD 21401

REGULATORY ACTION:

Submission of Me-Too Registration Request for Expel .

TRANSMITTAL DATE:

February 17, 2004

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE Number
	1 of 2	Transmittal Document	-
	2 of 2	Document Number 1: Product Identification and Disclosure of Ingredients	151-10 830.1100
	2 of 2	Document Number 2: Description of Beginning Materials and Manufacturing Process	151-11 830.1200

	2 of 2	Document Number 3: Discussion of the Formation of Impurities	151-12 830.1400
	2 of 2	Document Number 4: Certified Limits	158.175 830.1750

March  
30, 2004

COMPANY OFFICIAL: R. Bruce Jaeger

Signature: R. Bruce Jaeger

COMPANY NAME: Bikel Company, Ltd..

COMPANY CONTACT: R. Bruce Jaeger

AGENT/REPRESENTATIVE: R. Bruce Jaeger



United States  
Environmental Protection Agency  
Washington, D.C. 20460

Form Approved  
CMB No. 2070-0060  
Approval Expires 05-31-95

Certification with Respect to Citation of Data

Applicant's Name and Address: Bikel Company, Ltd Sudo Building 3rd Floor, 100-18 Samsung-Dong Kangnam-Ku, Seoul, Korea	EPA File Symbol/Registration Number: 81041-R
	Product Name: Expat
	Date of Application: February 17, 2004

**NOTE:** If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration this is an exclusive use study.

☐ I am the original submitter\*; or

☐ I have obtained the written permission of the original submitter for \_\_\_\_\_, which is

(insert name of chemical)

\_\_\_\_\_ (for multiple chemicals link the companies who are original data submitters

(insert names of companies)

with the appropriate chemical name) to cite that study\*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

a. ☐ I am the original data submitter\*; or

☐ I have obtained the written permission of the original data submitter for \_\_\_\_\_, which is

(insert name of chemical)

\_\_\_\_\_ (for multiple chemicals link the companies who are original data submitters

(insert names of companies)

with the appropriate chemical name) to cite that study\*; or

b. ☒ I have notified in writing the companies \_\_\_\_\_ for \_\_\_\_\_ that

(insert names of companies)

(insert name of chemical)

have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

Companies \_\_\_\_\_ for \_\_\_\_\_ (for multiple

(insert names of companies)

(insert name of chemical)

chemicals link the companies who are original data submitters with the appropriate chemical name) listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method\*). (Also, sign the General Offer Statement below.)

Companies \_\_\_\_\_ for \_\_\_\_\_ (for multiple



(insert names of companies)

(insert name of chemical)

chemicals link the companies who are original data submitters with the appropriate chemical name) that have submitted the studies which I have cited (Selective method\*).

4. ☐ I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

\* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature: 	Name and Title: R. Bruce Jaeger/ President, Health & Environmental Horizons, Ltd	Date: February 17, 2004
General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.		
Signature: 	Name and Title: R. Bruce Jaeger/ President, Health & Environmental Horizons, Ltd	Date: February 17, 2004

